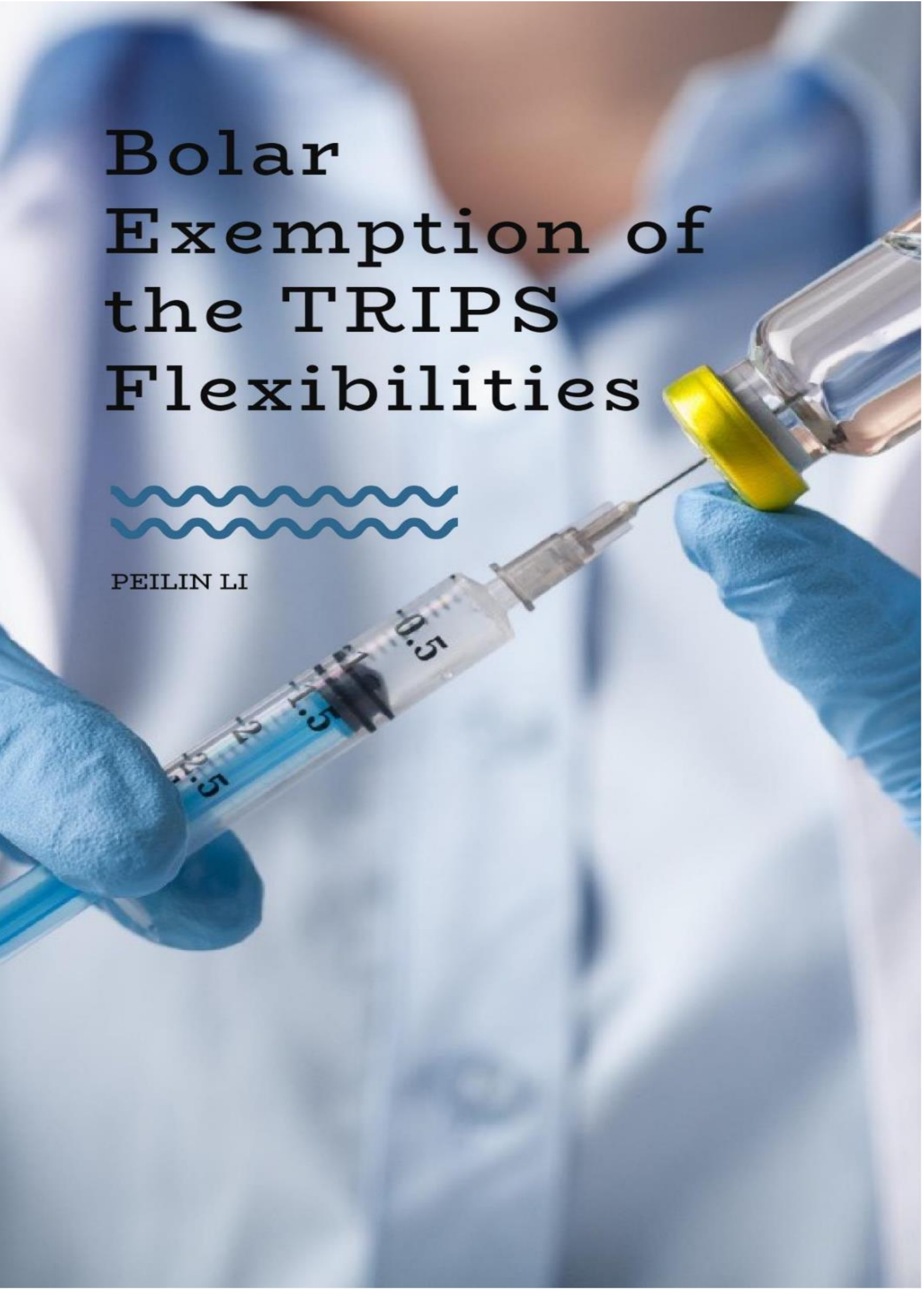


Bolar Exemption of the TRIPS Flexibilities

PEILIN LI

Bolar Exemption of the TRIPS Flexibilities:

A comparative analysis between the US, Finland and China, of patenting pharmaceuticals and access to vaccines during COVID-19

Bolar Exemption of the TRIPS Flexibilities:

A comparative analysis between the US, Finland and China, of patenting pharmaceuticals and access to vaccines during COVID-19

Peilin Li

Informyth

© 2023 Peilin Li

All rights reserved. No part of these publications may be reproduced, distributed, or transmitted in any form or by any means, including photocopying, recording, or other electronic or mechanical methods, without the prior written permission of the publisher, except in the case of brief quotations embodied in critical reviews and certain other noncommercial uses permitted by copyright law. Specific written permission must be obtained from the author for all copying.

Comparative Analysis of Legal Risks and Prevention in Pre-Sale Transactions for Unfinished Commercial Real Estate Projects
First printing 2023
ISBN 978-952-65260-0-3 (paperback)
ISBN 978-952-65260-1-0 (PDF)

Informyth

Trans-Atlantic Publishers Finland

Abstract

This book aims to address the existing obstacles caused by varying perspectives within the framework of the TRIPS agreement, which was established to bridge legal and practical gaps between jurisdictions worldwide. Specifically, it focuses on exploring the disparities and similarities in the Bolar exemptions of TRIPS Flexibilities for pharmaceutical patents across continents, with a particular emphasis on the Republic of Finland, the People's Republic of China (China), and the United States (the US). The research adopts a hierarchical approach, utilizing deductive theory, legal case analysis, and extensive literature review. By examining both international law and national legal systems, this study establishes a basis for comparing the three jurisdictions across different continents. Furthermore, it provides an evaluation of the advantages and disadvantages associated with implementing Bolar provisions in each country, particularly regarding access to vaccines during the COVID-19 pandemic.

Abbreviations

AIDS	Gained Immunodeficiency Syndrome
CAFC	Court of Appeals for the Federal Circuit
China	The People's Republic of China
EU	European Union
EFTA	European Free Trade Association
FTA	Free Trade Area
HIV	Human immunodeficiency virus
IP	Intellectual Property
IPR	Intellectual Property Rights
MSF	Médecins Sans Frontières
NAFTA	North American Free Trade Area
R&D	Research and Development
SPC	Supplementary Protection Certificates
TRIPS	Trade-Related Aspects of Intellectual Property Rights
MPP	Medicines Patent Pool
US	The United States
UN	United Nations
WTO	World Trade Organisation

Table of Contents

Abstract 5

Abbreviations 6

Table of Contents 7

1. Introduction 9
    - 1.1 Background & Problem description 10
    - 1.2 Objective & research questions 24
    - 1.3 Methodology 28
    - 1.4 Limitations 29
    - 1.5 Structure 31
2. Legal Foundation of Bolar Exemption 33
    - 2.1 The Relation of TRIPS on Pharmaceutical Patents to the Good of Public Health 34
    - 2.2 TRIPS Flexibilities 40
    - 2.3 Bolar Exemption under Health Crises 48
3. Developments and scenarios of Bolar exemption implementation in Finland, the US and China 63
    - 3.1 The Republic of Finland 64
    - 3.2 The US 77
    - 3.3 The People's Republic of China 88
4. Discussions and concluding remarks 100

4.1 Comparative law perspective 102
4.2 Advantages and disadvantages of Bolar Provision 105
4.3 Access to vaccines during COVID-19 108
4.4 Future research 109
Bibliography 111
International treaties 111
European Union Directives 112
National legislation 113
Case law 114
Papers 115
Articles 121
Other resources 135

1. Introduction

The summary provides an overview of the introduction section of a study that focuses on the implications of intellectual property rights and the Bolar exemption in relation to access to COVID-19 vaccines during health crises. The introduction highlights the global health crisis caused by the COVID-19 pandemic, emphasizing the challenges faced in terms of limited vaccine production and delivery. It discusses the lack of access to antiviral drugs and vaccines in developing countries and the impact of patent protection on global health crises. The legal background section explores the TRIPS Agreement and its influence on intellectual property rights, particularly in the pharmaceutical industry. It discusses the Doha Declaration on TRIPS and Public Health and the importance of balancing rights and obligations. The objective and research questions of the study are outlined, focusing on the effect of the Bolar exemption on pharmaceutical patents, access to medicines during health crises, and the differences between national legal systems in Finland, China, and the US. The methodology section explains the hierarchical method and deductive theory used to analyze applicable laws and regulations, case studies, and secondary sources. The limitations of the research are acknowledged, including the focus on selected countries and the exclusion of socio-economic influences. The structure of the study is also outlined, with the second chapter discussing legal foundations, the third chapter examining the implementation of the Bolar exemption in selected countries, and the fourth chapter providing a conclusion and proposed solutions.

1.1 Background & Problem description

The summary provided discusses the background and problem description related to the COVID-19 pandemic and the intellectual property (IP) issues surrounding vaccines and pharmaceuticals. The COVID-19 pandemic is recognized as a global health crisis and one of the most challenging events since World War II. The lack of vaccines and drugs has delayed the fight against the virus, and the complexity of medical technology access has worsened the situation.

Previous health crises, such as the Swine flu outbreak, have highlighted the challenges in accessing medical technology. Inadequate prioritization and public understanding have led to the use of drugs with limited evidence of efficacy and safety. Patent protection further complicates access to pharmaceuticals, as it limits the number of manufacturers and delays global access. This situation is repeating with COVID-19, where developing countries face difficulties in accessing treatments and vaccines due to limited supply and patent restrictions.

While some countries have developed their own vaccines, the global production of vaccines remains insufficient to meet the demand. Delivering vaccines accurately and quickly to countries in need is another challenge. Some countries have expressed support for waiving intellectual property protections for COVID-19 vaccines to address these issues. However, concerns are raised about the impact on innovation and the pharmaceutical industry.

The legal background is discussed, highlighting the TRIPS Agreement established in 1995, which aimed to secure intellectual property rights. Developed countries have pushed for stronger IP protection, but this has created financial burdens for developing countries. The Doha Declaration on TRIPS and Public Health emphasizes the need to balance IP rights with public welfare. However, TRIPS-plus provisions and the race to develop COVID-19 vaccines have raised concerns about the accessibility of vaccines in developing countries.

The summary concludes by emphasizing the importance of the global response and cooperation in addressing the pandemic. It suggests that countries should enact IP laws and policies tailored to their national and regional circumstances to speed up access to vaccines. The patent system grants temporary monopolies to inventors, but in the context of a global health crisis, securing global public health should be prioritized.

1.1.1 COVID-19 Pandemic as Health Crisis

Since the spring of 2020, the world has witnessed an outbreak of COVID-19 cases, which the the World Health Organisation (WHO) announced by its character a pandemic.[1] International society has thus broadly recognised that the COVID-19 constitutes a global health crisis of our time, as well as the most difficult challenge we have faced since World War II.[2] In just a few months since its emergence, the virus had spread across continents and across nationals, infected hundreds of millions and killed millions, making it undoubtedly one of the most influential health events of all time due to the lack of vaccines and drugs, the complexity of development of which delayed the fight against the virus and the complexity of medical technology access yet made it worse.

---

[1] WHO, ' WHO announces COVID-19 outbreak a pandemic', (12 March 2020) < https://www.euro.who.int/en/health-topics/health-emergencies/coronavirus-covid-19/news/news/2020/3/who-announces-covid-19-outbreak-a-pandemic> accessed 13 August 2021

[2] UNDP, 'COVID-19 Pandemic Humanity needs leadership and solidarity to defeat COVID-19' (23 March 2020) <https://www.tr.undp.org/content/turkey/en/home/presscenter/articles/2020/03/COVID-19-dayanisma.html?utm_source=EN&utm_medium=GSR&utm_content=US_UNDP_PaidSearch_Brand_English&utm_campaign=CENTRAL&c_src=CENTRAL&c_src2=GSR&gclid=CjwKCAjwgviIBhBkEiwA10D2jxHh0X_GwAU_0vR70bhkyMptJvk1dIHZhBZmY

Little has been learned from the experiences accumulated in dealing with previous health crises.[3] In 2012, the World Trade Organization (WTO) obtained data from UNICEF and WHO, proving that the complexity of medical technology access problems with children worldwide is greater than that of AIDS, Malaria, and Tuberculosis all combined.[4] In dealing with the Swine flu outbreak in 2002, with the initial supportive stance of the National Institute for Health and Care Excellence (NICE), the CDC, the WHO, and the ECDC in the EU and the US, recommended Oseltamivir (Tamiflu), a

---

FbvDE_WD8XpYFJp8hoCeAIQAvD_BwE> accessed 13 August 2021.

[3] ibid.

[4] WTO, Chapter 4: Medical technologies: the access dimension <https://www.wto.org/english/tratop_e/trips_e/trilatweb_e/ch4a_trilat_web_13_e.htm > accessed 20 May 2021

neuraminidase inhibitor (NIs), to treat and prevent influenza.[5] The drug was even stockpiled in preparation of a possible pandemic.[6] However, little was known about its efficacy and safety.[7] Later in 2014, the Cochrane Review findings concluded that there is a shortage of evidence supporting the use of NIs such as Tamiflu prophylaxis to prevent the person-to-person spread of influenza.[8] Because of the lack of prioritisation and public understanding, it is the governmental regulatory food and drug authorities (FDA) who should have put things in the proper order when the Cochrane Review was demonstrated.[9]

---

[5] Gupta, Yogendra Kumar, Meenakshi Meenu, and Prafull Mohan. 2015. The Tamiflu fiasco and lessons learnt. *Indian journal of pharmacology* 47 (1): 11–16. <https://doi.org/10.4103/0253-7613.150308> accessed 17 May 2021

[6] Gupta, Yogendra Kumar, Meenakshi Meenu, and Prafull Mohan. 2015. The Tamiflu fiasco and lessons learnt. *Indian journal of pharmacology* 47 (1): 11–16. <https://doi.org/10.4103/0253-7613.150308> accessed 17 May 2021

[7] ibid.

[8] Tom Jefferson and others, ‘ Neuraminidase Inhibitors for Preventing and Treating Influenza in Adults and Children.’ (2014) *Cochrane Database of Systematic Reviews.* <https://doi.org/10.1002/14651858.cd008965.pub4.> accessed 18 May 2021

[9] Cochrane Review < https://www.cochrane.org/> accessed 13 August 2021

The concern is established in pharmaceuticals, new and innovative products are protected by patents, extending the dimension to vaccines, a lack of technical skills and expertise ('know-how') are culpable for preventing an increasing number of producers from manufacturing the product.[10] In order to set up a decent vaccine manufacturing plan, a group of highly skilled people and technical experts with extensive knowledge in that particular vaccine area are needed.[11] However, the patenting issue would slow down the global access to pharmaceuticals.

Bearing that in mind, the cause of limited manufacturers of Swine Flu vaccines was less knowledge of know-how and the limited market for seasonal influenza vaccines in developing countries.[12] Unfortunately, governments are repeating the same scenario now with COVID-19 from the Swine Flu, which may cause more costly mistakes when resources are limited.[13] Health experts and access advocates indicate that the approach could leave developing countries in a difficult situation, where other states are pre-ordering doses when the current vaccine enters later-stage clinical trials.[14]

---

[10] WTO, 'Chapter 4: Medical technologies: the access dimension' <https://www.wto.org/english/tratop_e/trips_e/trilatweb_e/ch4a_trilat_web_13_e.htm#_ednref19> accessed 20 May 2021

[11] ibid.

[12] ibid.

[13] Grace Ren, 'Scramble To Preorder COVID-19 Vaccines May Leave Poorer Countries Behind.' (Health Policy Watch, 14 August 2020) <https://healthpolicy-watch.news/scramble-to-preorder-

Despite the efforts made by the developing countries, the antiviral drug, which was proved to be a promising treatment for COVID-19, was not available to them. The developed countries such as the US and EU have bought all the supply of Gilead, whilst other countries not covered by the Gilead license are not eligible to access them. [15]

By another way out of this perplexity, China has developed vaccines by state-owned company Sinopharm and got WHO emergency approval for COVID-19 vaccine.[16] The vaccine was distributed as emergency use, and included in

---

covid-19-vaccines-may-leave-poorer-countries-behind-threatening-global-response/> accessed 20 May 2021

[14] ibid.

[15] Vijay, Svět Lustig, 'Gilead Says Remdesivir Shortages Due To Supply Chain Issues, Civil Society Argues For Wider Licensing. *Health Policy Watch*.' (3 September 2020) <https://healthpolicy-watch.news/gilead-says-remdesivir-shortages-due-to-supply-chain-issues-civil-society-argues-for-wider-licensing/> accessed 18 May 2021

[16] BBC, 'Sinopharm: Chinese covid vaccine gets WHO emergency approval' (7 May <https://www.bbc.com/news/world-asia-china-56967973> accessed 22 May 2021

COVAX to facilitate access to hundreds of millions of people in China and elsewhere, to individual health regulators in poorer countries like Africa, Latin America, and Asia. [17] Contrarily, in a developing country such as India, it appears that its second wave of COVID-19 surge is much worse than the previous first, [18] and it is likely to make global shortages even worse.[19]

A worldwide pandemic requires major countries to unite cooperatively to battle against the virus. However, the insufficient production of vaccines is a major challenge in the global response to the pandemic. Another issue is the inability to deliver vaccines to countries and regions in need, quickly and accurately. The step forward is that there are countries who expressed support for waiving intellectual property protections for COVID-19 vaccines. [20] In the US it means that if local companies are going to sue other countries for imitating their parents, the US government will not endorse the claims at the WTO.[21] In the EU, drug producers such as Pfizerin Germany argued by stating that waiving intellectual property protections would strangle innovations.[22] The pharmaceutical industry is said to suffer if pharmaceutical companies lose their intellectual property. They must be persuaded by the fact that the COVID-19 pandemic is much more than a health crisis, and requires all industries, governments and organisations to cooperate in the efforts and balance common interest.[23] Under complicated situations such as the occurrence of a pandemic, in order to speed up access to vaccines, each country must enact IP laws and policies that are best suited to its national and regional circumstances and capabilities.

---

[17] ibid.

[18] Josh Ulick, ‘ Why India’s second covid-19 surge is much worse than its first.’ (15 May 2021) Wall Street Journal <https://www.wsj.com/articles/why-indias-second-covid-19-surge-is-much-worse-than-its-first-11621071001> accessed 22 May 2021

[19] Diksha Madhok, ‘India’s COVID-19 catastrophe could make global shortages even worse’ (11 May 2021) CNN Business <https://edition.cnn.com/2021/05/10/business/india-covid-industries-intl-hnk/index.html> accessed 22 May 2021

[20] Emma Bowman, and Ashish Valentine, ‘ Biden Backs Waiving International Patent Protections For COVID-19 Vaccines’, (NPR, 5 May 2021), < https://www.npr.org/sections/coronavirus-live-

1.1.2 Legal Background

---

updates/2021/05/05/993998745/biden-backs-waiving-international-patent-protections-for-covid-19-vaccines?t=1628880651447> accessed 13 August 2021

[21] ibid.

[22] ibid.

[23] UNDP, 'COVID-19 Pandemic Humanity needs leadership and solidarity to defeat COVID-19 <https://www1.undp.org/content/brussels/en/home/coronavirus.html> accessed 13 August 2021

When the TRIPS Agreement was established in 1995, it was designed as the first comprehensive international agreement to secure all nameable IP rights. [24] The Agreement included patent protection, which is awarded to any type of inventions and also pharmaceutical patents.[25] It is believed by the policymakers in developed countries that TRIPS will increase the knowledge of IP protection levels worldwide; however, the actual result is not always believed satisfactory.[26] Since the creation of the intellectual property concept, developed countries have demanded to strengthen IP protection because they are net exporters of IP -related goods and services.[27]On the other hand, many of the developing countries are facing the fact that they have to bear a heavy financial burden if they import and use these goods, and services. As regard to health, the TRIPS "has had and will have" comprehensive influence on third-world economies.[28]

---

[24]The Agreement on Trade-Related Aspects of Intellectual Property Rights, 15 April 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994)

[25] ibid.

[26] ibid.

[27] Sell Susan K, *Private Power, Public Law: the Globalisation of Intellectual Property Rights* (Cambridge University Press 2003)

According to WHO, there are currently 4.8 billion people living in developing countries and 43% of them live on less than 2 USD a day.[29] Spending on health care cannot always be ensured. With unsatisfactory nutrient conditions and difficult hygienic facilities, communicable disease always poses a problem and makes up half of the diseases in the developing countries.[30] Lack of drugs and other medical resources make living there even worse.

The Doha Declaration on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and Public Health (or the Doha Declaration in short) was adopted by WTO members, who commit to promote innovation, exchange of technology, and guard public welfare.[31] The central concern of The TRIPS is multidimensional.[32] The purpose of protecting and enforcing intellectual property rights, according to Article 7, is to promote technological invention and communication, to ensure mutual benefits of producers and users of technological knowledge in a productive approach for both social and economic welfare, and to balance rights and obligations.[33] Drugs and other products are covered by the agreement.[34]

---

[28] Cullet Philippe. Patents and Medicines: the Relationship between TRIPS and the Human Right to Health. International Affairs (Royal Institute of International Affairs 1944-) Vol. 79, No. 1 (Jan., 2003), pp. 139-160.

[29] WHO. The Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property <https://www.who.int/phi/implementation/phi_globstat_action/en/> accessed 15 April 2021

[30] ibid.

[31] WTO South-East Asia, UHC Technical brief, 'Public health protection in patent laws: selected provisions'.

According to the WTO rules, almost every member of the WTO had to reform their IP laws in order to comply with the minimum standards of protection that TRIPS advised.[35] For most TRIPS member states that are net-importers, this unprecedented harmonising treaty would assure an international minimum standard for the IP, and not as a barrier for ongoing international processes of Intellectual property rights (IPRs) expansion.[36] As Paster pointed out , we now live in a post-TRIPS era.[37] Ample evidence shows that the TRIPS-plus provisions, though not formally related to the original TRIPS Agreement, have a rather negative impact affecting accessibility to and availability in developing countries.[38] TRIPS-plus is a higher level of protection in norms demanded by the developed countries that are not prescribed by the WTO's TRIPS Agreements. [39]

---

[32] ibid.

[33] WHO OMC, 'TRIPS and Pharmaceutical Patents', < https://www.wto.org/english/tratop_e/trips_e/tripsfactsheet_pharma_e.pdf> accessed 14 August 2021

[34] ibid.

[35] Pastor, Rafael. The impact of free trade agreeements on intellectual property standards in a post-TRIPS world <https://www.bilaterals.org/?the-impact-of-free-trade&lang=en> accessed 21 May 2021

[36]ibid.

The global race in developing Covid-19 vaccines,[40] [41] [42] as well as country-specific reactions and methods on patent regulations to accelerate vaccine accessibility has brought many concerns about the global Intellectual Property system.[43]

---

[37] Pastor, Rafael. The impact of free trade agreements on intellectual property standards in a post-TRIPS world <https://www.bilaterals.org/?the-impact-of-free-trade&lang=en> accessed 21 May 2021

[38] Armounti, Wael. Evolution of data Exclusivity for pharmaceuticals in Free Trade Agreements. Policy Brief 7, April 2020 < https://www.southcentre.int/tag/trips-plus-provisions/> accessed 21 May 2021

[39] Armounti, Wael. Evolution of data Exclusivity for pharmaceuticals in Free Trade Agreements. Policy Brief 7, April 2020 < https://www.southcentre.int/tag/trips-plus-provisions/> accessed 21 May 2021

[40] European Patent Convention (EPC) Art. 87(1) and (4)

[41] U.S.C. 35 § 102 on First Inventor to File (FITF) <https://www.uspto.gov/patents/first-inventor-file-fitf-resources> accessed 09 April 2021

[42] China Patent law of the people's republic of china, industrial property , June 1993, text 2-001, page 004 Chapter 1 (9) Where two or more applicants file applications for patent for the identical

The patent system adoption varies slightly in each domestic law. A European Patent will be granted by the European patent office (EPO). In Finland, it is called "Patentti- ja rekisterihallitus" (PRH). A United States Patent application is examined in the United States Patent and Trademark Office (USPTO). Chinese patent applications are processed in China National Intellectual Property Administration (CNIPA). Regardless of the place of granting a patent, a temporary monopoly for the exploitation of a useful invention belongs to the inventor. [44] [45] [46] There is no doubt that the manufacturer

---

invention-creation, the patent right shall be granted to the applicant whose application was filed first. Retrieved 09.04.2021, from <https://www.wipo.int/edocs/lexdocs/laws/en/cn/cn006en.pdf > accessed 09 April 2021

[43] ibid.

[44] 52002AE1031. Opinion of the Economic and Social Committee on the "Proposal for a Directive of the European Parliament and of the Council on the patentability of computer-implemented inventions" (COM(2002) 92 final - 2002/0047 (COD)) Official Journal C 061, 14/03/2003 P. 0154 -0163 Section 1.1

[45] United States Patent and Trademark office (USPTO) <https://www.uspto.gov> accessed 9 April 2021

[46] China National Intellectual Property Administration (CNIPA) <https://www.cnipa.gov.cn> accessed 9 April 2021

who successfully made a COVID-19 vaccine makes a significant contribution to securing global public health.

1.2 Objective & research questions

The summary provided outlines the focus and objectives of a research project related to intellectual property rights, specifically exploring the Bolar provisions and their implications in different legal systems. While comparative legal studies have been conducted on Bolar provisions between the US and China, as well as between the US and the EU, there is limited research on comparing Bolar provisions between Finland, the US, and China.

Additionally, the research aims to investigate the challenges faced by generic medicines entering developing countries, which have different circumstances compared to net-exporting countries like the US and the EU. By comparing China with the US and Finland, the study aims to understand the different approaches taken by countries at different stages of development.

The primary objective of the research is to enhance understanding of the implications of the Bolar exemption in the context of the TRIPS Agreement, particularly in relation to vaccine patents during health crises. The research will address several secondary questions related to access to vaccines during health crises, such as the effects of Bolar exemption on pharmaceutical patents, access to medicines, and the similarities and differences in national legal systems of Finland, China, and the US regarding the Bolar exemption. The advantages and disadvantages of utilizing the Bolar exemption will also be explored. Furthermore, the research aims to analyze the current situation in China as a developing country in terms of access to vaccines.

Overall, the research project intends to provide insights into the various aspects of Bolar provisions, their impact on access to vaccines during health crises, and the differences in approaches taken by different countries with regard to the Bolar exemption.

***

Intellectual property rights have been a hotspot in legal research in recent decades. Abundant achievements have been made on different topics through different approaches. Bolar provisions fall into such a research focus. Comparative legal studies have been carried out on application of Bolar provisions between the

US and China, [47] [48] and between the US and the EU. [49] [50] However, little research has evaluated comparing legal systems on Bolar provisions between Finland, the US, and China.

At the same time, studies and research have been done to investigate the difficulties for generic medicines entry into developing countries, as they are not the net-exporter situations as the US and the EU. [51] [52] [53] By comparing between China and the US as well as between China and Finland, this research also seeks to clarify different approaches between countries of different developing levels.

---

[47] Yuhe Wu and Yanfeng Xiong, '*Comparison Of Bolar Exception In China And The United States*' (China Patents & Trademarks Publications 2008).

[48] Li Feng, Jiancheng Jiang, Yuan Wang. China: Experimental use exemption of patent infringement - a brief comparison of China and the United States. (16 February 2015) Wan hui da - Peksung IP group <https://www.mondaq.com/china/patent/374754/experimental-use-exemption-of-patent-infringement--a-brief-comparison-of-china-and-the-united-states> accessed 22 May 2021

[49] Wested Jakob and Timo Minssen, 'Research and Bolar Exemptions in the US and Europe: Recent Developments and Possible Scenarios.' *Available at SSRN 3236127* (2018).

[50] Jakob Wested and Timo Minssen, ' Update on Research- & Bolar Exemptions in the U.S. and Europe: Unsolved Questions and New Developments in an Increasingly Important Area of Law ' NIR: Nordiskt Immateriellt Rättsskydd, Vol. 2019, No. 2, pp. 168-183 <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3360277> accessed 22 May 2021

The aim of this research is to facilitate understanding of the differences in implication of TRIPS Agreements, especially Bolar exemption of TRIPS flexibilities regarding vaccine patents in health crises by comparing national legal systems such as Finland, China, and the US. The study will discuss the following supportive secondary questions emphasising on access to vaccines during the health crisis:

---

[51] Jing Chen, Xiaoyan Nie, Peng Yao, Luwen Shi. 'TRIPS -plus and access to medicines in China', Journal of Public Health policy 34, 226-238(2013) < https://link.springer.com/article/10.1057/jphp.2013.13> accessed 21 May 2021

[52] Rohit Malpani. All cost no benefit: How TRIPS-Plus intellectual property rules in the US-Jordan FTA affect access to medicines. Oxford, UK: Oxfam International. Oxfam Briefing Paper No. 102, <http://donttradeourlivesaway.files.wordpress.com/2011/01/all-costs-no-benefits.pdf>, accessed 21 May 2021

[53] Nusaraporn Kessomboon, Jiraporn Limpananont, Vithaya Kulsomboon, Usawadee Maleewong, Achara Eksaengsri, Prinya Paothong. Impact on access to medicines from trips-plus: a case study of THAI.US FTA (May 2010) The Southeast Asian Journal of tropical medicine and public health 41 (3): 667.77 PubMed. < https://www.researchgate.net/publication/44800555_Impact_on_access_to_medicines_from_trips-plusA_case_study_of_THAI-US_FTA> accessed 21 May 2021

- What is the effect on pharmaceutical patents of Bolar exemption in relation to health crises in the US, Finland and China?
- And what are the effects Bolar exemption has on access to medicines during health crises?
- The differences and similarities while comparing the Finland, China and the US national legal systems to Bolar exemption regarding health crisis?
- What are the advantages and disadvantages of using the Bolar exemption?
- What scenarios and current situations does a developing country such as China have in regard to the access to vaccines?

1.3 Methodology

To address the research questions, a hierarchical method of applicable laws was used to assist the comparative inter-system between Finland, China, and the United States on pharmaceutical patent rules under the Doha Declaration on TRIPS and Publish Health. Additionally, a deductive theory is used to investigate the relevance of the existing regulatory exemption, known as the Bolar exemption, under the TRIPS agreement in terms of accessing vaccines during health crises in these three systems.

To analyse the impact of the patent law on access to medicines between Finland, China and the US in the context of Bolar exemptions, is to review each system specific patent law, case laws and relevant administrative legislation to see the TRIPS flexibilities, especially Bolar exemption implementation situation under system-specific context.

In addition, TRIPS-plus provisions are reviewed for suggestive methods for China in resisting these alliance provisions between the EU and the US. Lastly, while collecting and sorting out the relevant information from scholarly papers and articles, industry reports, the factual enforcement role of importance, and the advantages and disadvantages of the Bolar provisions will be identified.

Overall, the research materials consist mainly of primary laws, case studies, previous related research (if any), and secondary sources such as articles, legal journals, and seminars (recorded or transcribed).

1.4 Limitations

This research is limited to comparative research on the national legal systems of Finland, the US and China regarding pharmaceutical patents, especially the Bolar exemption in access to vaccines during health crises. A drawback of the research is that the Bolar exemption may not have a direct impact on access to pharmaceutical vaccines in the context of pandemic. However, any relevant information is mentioned in the context of the theoretical framework of the legislation regarding patent law.

It is opined that many other factors such as socio-economic influences also determine access to pharmaceutical patents, and the speed accessing of pharmaceuticals is rarely due to these two single determinants, which is not addressed in this study, as they are not part of the interface on the comparative legal study of governmental patent regulations, public health and trade.

This research does not take into consideration narrower institutional cases such as Universities that have a long tradition to voluntarily impose restraints and adopt policies in the patent governance methods. In addition, this research does not dive into private companies that have similar lenient activities regarding their patent inventions. Therefore, this research mainly focuses on the regulatory level regime pertaining to pharmaceuticals and their access to three different perspectives such as in the US, Finland and China under the health crisis. Thus, the findings derived from the research could not represent all similarities and differences between the three systems.

However, the materials used are limited since every material used in this research has to be in interpretable language, in English, therefore foreign sources taken into consideration to support the arguments are left out what would contribute of greater significance to the research.

In order to make research feasible, the research area has been narrowed down to the national level, taking into account selected countries such as Finland, the US, and China comparing their implementation with Bolar provision regarding pharmaceutical patents.

1.5 Structure

Following this introduction, the second chapter of the study will discuss the legal foundations based on the TRIPS and public health, Doha Declaration as well as Bolar Exemptions and their influence on the accessibility to new technology as regard to development of COVID-19 drugs, particularly, vaccines. The chapter also delves into the difficulties associated with putting Bolar provisions into action for the sake of public health.

The third chapter examines the developments and potential outcomes of Bolar exemption implementation in Finland, the United States, and China separately, and comparison between these countries in particular. This is designed to investigate both similarities and differences between developing countries and developed countries, but also to find similarities and differences within the class of developed countries in the American and European continents. The central topic is focused on the legal basis on how access to COVID-19 vaccines in these countries has been legally defined.

The fourth chapter concludes the entire study, revealing the findings of the comparative study, summarising advantages and disadvantages of the Bolar Provisions, and giving a tentative solution to the problem of access to vaccines during COVID-19 pandemic.

2. Legal Foundation of Bolar Exemption

The legal foundation of the Bolar exemption, which allows generic drug manufacturers to obtain marketing permission for pharmaceutical products before the expiration of patents, is based on international agreements such as the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). TRIPS aims to strike a balance between long-term social objectives and short-term goals by providing patent protection while allowing certain provisions to ensure accessibility to medicines.

Under TRIPS, member states are obligated to provide patent protection for inventions that meet certain criteria, including novelty, inventive step, and industrial applicability. However, there are exceptions to patenting in the context of public health, such as inventions that could exploit human, animal, or plant life or health. Article 30 of TRIPS allows countries to limit patent rights through exceptions if it does not unreasonably exploit the patent.

TRIPS also includes flexibilities that support public health, including the Bolar provision. The Bolar exemption allows generic manufacturers to conduct research and seek marketing authorization for pharmaceutical products before the patent expires. This provision is particularly important during health crises, as it facilitates timely access to medications. However, practical obstacles and variations in the implementation of Bolar exemptions exist among countries.

Challenges in implementing Bolar provisions during health crises include the need for a case-by-case approach, limitations in national legislation, and the complexity of the intellectual property system. Intellectual property (IP) tools, such as secondary patents and patent thickets, can also act as barriers to the entry of generic and biosimilar medicines into the market.

Overall, the legal foundation of the Bolar exemption and other TRIPS flexibilities plays a crucial role in promoting access to medicines, especially during health crises. However, addressing challenges and ensuring efficient implementation of these provisions remains an ongoing concern.

2.1 The Relation of TRIPS on Pharmaceutical Patents to the Good of Public Health

The implementation of intellectual property pragmatism, particularly patents on drugs, can hinder heavily accessibility of medicines. For example, it is probably that the price of medicines rises suddenly, the motivation of local producers is reduced, or the motivation of research and development is increased. As a result, accessibility to medicines would become difficult. Therefore, realisation of intellectual property rights strictly could directly lead to difficult accessibility to the human right to health.[54] The WTO Doha Declaration on TRIPS and Public Health was agreed by WTO members in 2001, from a structured public health policy regarding intellectual property systems.[55] However, it has been struggling for international law to account for human rights and economic development.[56]

The philosophy of TRIPS is to balance both the long term social objectives by providing incentives for future inventions and creations, and short term goals in allowing the use of existing inventions and creations.[57] WTO members are obliged to provide patent protection for any invention belonging to a product or process, while allowing certain provisions stated in Article 27.1.[58] In Article 33, terms of protection shall end on the expiration date of the period of twenty years from the date of filing. [59] Implying context of non-discrimination, Member State cannot discriminate against different fields of technology in their patent regimes.[60] Nor can Member States discriminate against the place of the invention or if the product is imported or produced locally. [61]

---

[54] Cullet Philippe. Patents and Medicines: The Relationship between TRIPS and the Human Right to Health. International Affairs (Royal Institute of International Affairs 1944-) Vol. 79, No. 1 (Jan., 2003), pp. 139-160.

[55] WTO. TRIPS and publish health <https://www.wto.org/english/tratop_e/trips_e/pharmpatent_e.htm> accessed 19 May 2021

[56] WTO. Agreement on Trade-Related Aspects of Intellectual Property Rights (as amended on 23 January 2017) <https://www.wto.org/english/docs_e/legal_e/31bis_trips_01_e.htm>accessed 19 May 2021

[57] WTO. TRIPS and Pharmaceutical patents fact sheet (WTO OMC, September 2006) p.1<https://www.wto.org/english/tratop_e/trips_e/tripsfactsheet_pharma_2006_e.pdf> accessed 23 July 2021.

Despite the facts listed above, there are three criteria to be fulfilled in order to qualify for a patent, such that an invention should have a sense of "novelty", and it is compulsory to have an "inventive step" and not "obvious", also " industrial applicability". [62] Last but not least, details of the invention shall be described in the application while made public.[63] Member States are able to require the applicant to disclose the details of the invention as well as the best practices of carrying out the product or process. [64]

---

[58] The TRIPS Agreement Article 27 section 1. Subject to the provisions of paragraphs 2 and 3

[59] The TRIPS Agreement Article 33.

[60] The TRIPS Agreement Article 27.1

[61] ibid.

[62] ibid.

[63] ibid.

In the context of public health, Member State can refuse to grant patents, where the inventions could possibly commercially exploit human, animal or plant life or health according to Article 27.2 [65] Certain circumstances that enable methods that are diagnostically, therapeutically and surgically, able to treat humans or animals listed in Article 27.3a. [66] Also, stated in Article 27.3b, particular plants and animal inventions are excepted from patenting. [67] Further, under the TRIPS Agreement Article 30, Members are able to limit exceptions to patent rights, if certain conditions do not exceed "unreasonable" exploitation of the patent.[68]

Article 30 indicates that countries may allow generic drug manufacturers to obtain marketing permission from the public health authorities without the approval of the patent owner and even before the expiration of the patent. [69] The TRIPS Agreement Articles 8 and 40 give Members the power to act preventively towards patent owners and other holders of IP rights from abusing IP rights, such as unreasonably restraining trade, or hampering the international transfer of technology.[70]

---

[64] The TRIPS Agreement Article 20.1 Article 29.1

[65] The TRIPS Agreement Article 27.2

[66] The TRIPS Agreement Article 27.3a

[67] The TRIPS Agreement Article 27.3b

[68] The TRIPS Agreement Article 30.

[69] ibid.

Relevantly, Article 30 of TRIPS Agreement provides its Members who can "provide limited provisions to the exclusive rights conferred by a patent, provided that such provisions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties. " Additionally, Article 31 indicates a set of the "other uses without authorisation of the right holder", which includes the eligible use by the government or third parties authorised by the government, and which are not outlined in Article 30. [71]

2.1.1 Member Governments Obligations

---

[70] ibid.

[71] WTO, Part II- Standards concerning the availability, scope and use of intellectual property rights section 5 and 6. https://www.wto.org/english/docs_e/legal_e/27-trips_04c_e.htm > accessed 23 July 2021.

There are certain obligations under the TRIPS Agreement for Member States on patenting pharmaceuticals.[72] According to TRIPS Article 27.1 Member States are required to obtain patenting for any inventory objects which includes products such as medicine or a process that can be a method to produce chemical ingredients for a medicine. Article 27.1 further rules that Member States should not discriminate between "different fields of technology" in their patent regimes, or "place of invention" or if the products are "imported or locally produced".

In addition, Article 27.1 outlines that there are three criteria for qualifying a patent: such a patent shall be "novel" and including the "inventive step" and "industrial applicability" meaning that it must be useful as an invention. Article 29.1 demands that the invention should file the application with the invention of detailed description which will be made public. Moreover, the applicant may be required to disclose the best method to carry out the invention. Article 33 indicates that patent protection lasts at least 20 years from the date of the filing of the patent application.

---

[72] ibid.

2.2 TRIPS Flexibilities

Most of the flexibilities were settled at the Doha Ministerial Conference in November 2001 and member governments came to the conclusion that the TRIPS Agreement shall be interpreted in such a way supporting public health, to ease up access to existing medicines as well as create new medicines.[73] The term "flexibilities" became popular especially after the Doha Declaration on TRIPS and Public Health expressing TRIPS "flexibilities" used by trade negotiators within the IP community. [74]

Furthermore, the phrase "flexibility" appears in several provisions, including paragraphs 6 of the TRIPS Agreement's preamble: "[...] the special needs of the least-developed country Members in respect of maximum flexibility in the domestic implementation of laws and regulations in order to enable them to create a sound and viable technological base." Article 66.1 explains the definition of the word "flexibility" as it appears in the Preamble: "In view of the special needs and requirements of least-developed country Members, their economic, financial and administrative constraints, and their need for flexibility to create a viable technological base, such Members shall not be required to apply the provisions of this Agreement, other than Articles 3, 4 and 5, for a period of[...]"

---

[73] ibid.

[74] ibid.

In 2011, the UNAIDS/WHO/UNDP policy brief for economies to use the TRIPS flexibilities reported an increased access to HIV/AIDS treatments.[75] However, practical obstacles exist in using Bolar exemptions.[76] In the long struggle for bridging disagreements and balancing the benefits of different players, only limited but useful achievements have been made.

2.2.1 Article 31 experimental use of early working/'Bolar provision

The Bolar provision, in conjunction with research provisions, is used to advance science and technology.[77] It is supplemented by a more general research exemption, which is an exemption from infringement of specific research activities. In addition, Bolar exemption does have a basis in EU law whereas research exemption has its scope varying significantly from a country to another.[78] Because researchers may use a patented invention for research and to better understand the invention.[79]

---

[75] WIPO. SCP/31/5 Annex I, page 7 (23) <https://www.wipo.int/edocs/mdocs/scp/en/scp_31/scp_31_5.pdf> accessed 17 April 2021

[76] ibid.

[77] ibid.

The Bolar exemption to the TRIPS Agreements serves as a mechanism to expedite governments' access to medications during a health crisis.[80] A corporation may perform actions to seek marketing authorisation for a pharmaceutical product before the patent expires for the protection of the active substance of the original medicinal product under the Bolar exemption.[81] Furthermore, the grey area of marketing and selling under the Bolar exemption is when a company freely markets and sells a generic version of a patented drug for the express purpose of testing. [82]

---

[78] Pinsent Masons, 'Broadening safe harbours and patent exemptions for pharmaceuticals in Europe' (Outlaw, 26 February 2020) ,<https://www.pinsentmasons.com/out-law/analysis/safe-harbours-patent-exemptions-pharmaceuticals-europe> accessed 27 July 2021

[79] WTO. ' TRIPS and Pharmaceutical patents fact sheet' (WTO OMC, September 2006) p1<https://www.wto.org/english/tratop_e/trips_e/tripsfactsheet_pharma_2006_e.pdf> accessed 23 July 2021

[80] ibid.

[81] European Commission (EC), ' Commission staff working document of the Regulation' (Brusself, 25.11.2020) No 469/2009 SWD 292 Final <https://ec.europa.eu/docsroom/documents/43847/attachments/2/translations/en/renditions/native> accessed 15 August 2021

It has been revealed that despite the significant decrease of price, it has been still a critical factor obstructing obtaining HIV treatment in Low-and middle-income countries (LMICs).[83] Previous findings proved that the application of TRIPS flexibilities, have a positive impact on accessing treatments.[84] Thailand invoked compulsory licensing due to failure to negotiate a suitable price for the HIV/AIDS drug Kaletra (lopinavir/ritonavir) with Abobott in 2007.[85]

According to UNAIDS and WIPO research, among 142 countries, 95 of them have available data indicating that 56% actually implemented the TRIPS flexibilities including Bolar provision into their national patent legislation.[86] The study also found that the percentage of countries implementing the flexibilities varies from 0% for the least developed countries to 93% for high-income countries. [87] The inequality of economic development and unbalanced quality of living make the gap unfortunately unignorable. While the LMICs have had little access to innovative achievements in technological developments, there is also a lack of response to such issues in their legal systems. Even worse, there has long been an idea that taking intellectual property protection as negatively affecting the affordability and availability of access to pharmaceuticals.[88]

---

[82] ibid.

[83] WIPO. SCP/31/5 Annex I, page 7 (23)<https://www.wipo.int/edocs/mdocs/scp/en/scp_31/scp_31_5.pdf> accessed 17 April 2021

[84] ibid.

[85] ibid.

[86] UNAIDS Box 3: WIPO study on patent-related flexibilities in 142 countries <https://www.unaids.org/sites/default/files/media_asset/JC2049_PolicyBrief_TRIPS_en_1.pdf> accessed 17 May 2021

On the other side of the coin, there is the issue of patent infringement which is the commission to prohibit any acts without respect to a patented invention from the patent holder.[89] Licenses are therefore granted to such a permission.[90] Patent infringement varies in jurisdictions, and it generally includes the use or sale of the patented invention. [91]

According to the WIPO, the objective and goals of the Bolar exemption of the **regulatory review provision** in countries are to avoid a de facto extension of the patent term.[92] Bolar exemption is to aid in the marketing of generic medicines immediately after the patent term expires,[93] to boost market competition.[94] Furthermore, competition lowers product prices, which promotes the affordability of patent-expired medicines, reducing access to and the cost of treatment.[95]

---

[87] ibid.

[88] Sell Susan K, '*Private Power, Public Law: the Globalization of Intellectual Property Rights*' (Cambridge University Press 2003)

[89] WIPO<https://www.wipo.int/export/sites/www/sme/en/documents/pdf/ip_panorama_3_learning_points.pdf> 31 May 2021

[90] ibid.

[91] ibid.

The regulatory review provision is a mechanism to increase competition and, as such, should be recommended in developing countries to apply to their patent laws, among other provisions outlined in the WHO Global Strategy and Plan of Action on Public Health, Innovation, and Intellectual Property, which calls everyone to action to implement TRIPS flexibilities by allowing them to be incorporated into national laws.[96]

---

[92] WIPO, SCP/27/3 Standing Committee on the Law of Patents. Twenty -Seventh Session Geneva, (11 -15 December 2017) <https://www.wipo.int/edocs/mdocs/scp/en/scp_27/scp_27_3.pdf > accessed 14 May 2021

[93] WIPO, SCP/27/3 Standing Committee on the Law of Patents. p 4, objectives and goals 4.

[94] ibid.

[95] WIPO, SCP/27/3 Standing Committee on the Law of Patents. pa 17 and 18.<https://www.wipo.int/edocs/mdocs/scp/en/scp_27/scp_27_3.pdf >accessed 14 May 2021

[96] WIPO, 'The Global Strategy and Plan of action on public health, innovation and Intellectual Property'

Member States of WIPO administered treaties have a certain degree of manoeuvre to implement their obligations.[97]

Moreover, a separate declaration on TRIPS and Public health is made.[98] Member governments were granted that TRIPS Agreement will not prevent them from taking measures on protection of public health.[99] The Least Developed Countries until 2016 are granted the extension on pharmaceuticals for patent protection in regard to the TRIPS agreement.[100] Countries rather use TRIPS flexibilities than going under the Doha Declaration Paragraph 6 Waiver mechanism because it is too lengthy and trivial a procedure.[101] TRIPS flexibilities have provisions that are “public health sensitive” including Article 6 exhaustion parallel imports, Article 31 experimental use of early working/”Bolar provision”

<https://www.who.int/phi/implementation/phi_globstat_action/en/>accessed 14 May 2021

[97] WIPO, ‘Meaning of flexibilities’ <https://www.wipo.int/ip-development/en/agenda/flexibilities/meaning_of_flexibilities.html> accessed 8 June 2021

[98] ibid.

[99] ibid.

[100] ibid.

[101] ibid.

and Article 31 in the TRIPS Agreement compulsory licensing.[102]

The advantageous utilisation of TRIPS flexibilities, especially Bolar exemption, would positively impact access to the COVID-19 vaccines during health crises.[103] [104] During the COVID-19 pandemic, discussions about patent protection, reasonable access to technological knowledge, and balancing the innovator and the end-user were a focus in both the private and public sectors in regards to the creation of new vaccines and medications to combat the disease. TRIPS flexibilities have been credited as allowing economies to address the pressing public health crisis.

---

[102] WHO, 'Access to affordable medicines for HIV/AIDS and hepatitis: the intellectual property rights context.' Chapter 3 <https://apps.who.int/iris/bitstream/handle/10665/204741/B5144.pdf?sequence=1> accessed 14 May 2021

[103] WTO. TRIPS 31bis. <https://www.wto.org/english/docs_e/legal_e/31bis_trips_01_e.htm> accessed 19 May 2021

[104] Doha WTO Ministerial 2001: TRIPS WT/MIN(01)/DEC/2 Declaration on the TRIPS agreement and public health adopted on 14 November 2001.< :https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm> accessed from 9 April 2021

2.3 Bolar Exemption under Health Crises

2.3.1 Importance of Bolar exemption

Patent owners are granted exclusive rights under the TRIPS agreement to prevent anyone from making, using, offering for sale, selling, or importing patented products, which are exempted by Articles 30 and 31.[105] Furthermore, Article 30 allows Member States to make provisions for exclusive patent rights, and such provisions must meet three cumulative conditions, referred to as the three-step test: the provisions must be limited; they must not be unreasonably conflicted with the normal exploitation of the patent; and they must not unreasonably prejudice the patent owner's legitimate interest, taking into account of the legitimate interests of third parties.[106]

The "regulatory provision" refers to the situation in which generic manufacturers can continue to offer their copies of medications after the patent expires.[107] Bolar Provision' is used by Member States to advance science and technology, by allowing researchers to use patented inventions for research to understand the invention.[108] It allows generic firms to exploit patent-protected inventions to acquire marketing authorisation without the agreement of the patent owners, allowing them to market the items after the patent expires. [109] It further permits the use of patented knowledge for the development of information required for regulatory and market-entry approval during the patent term.[110]

---

[105] The TRIPS Agreement Article 30, 31

[106] The TRIPS Agreement Article 30

[107] WTO, 'FACT SHEET: TRIPS AND PHARMACEUTICAL PATENTS Obligations and exceptions' (World Trade Organisation, 2021) <https://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm#Bolar> accessed 19 May 2021

The importance of bolar exemption amid global health crises is demonstrated. Some nations, according to Article 30, enable generic medication producers to exploit a protected invention to get marketing authorisation from public health authorities without the patent owner's approval or knowledge, and before the patent protection expires. [111]

---

[108] ibid.

[109] WHO, Access to affordable medicines for HIV/AIDS and hepatitis: the intellectual property rights context. 3. TRIPS flexibilities and compulsory licensing. <https://apps.who.int/iris/bitstream/handle/10665/204741/B5144.pdf?sequence=1>accessed 14 May 2021

[110] ibid.

[111] WTO, 'FACT SHEET: TRIPS AND PHARMACEUTICAL PATENTS Obligations and exceptions' (World Trade Organisation, 2021)

To launch a pharmaceutical product, the company must first seek regulatory approval while undertaking clinical studies and trials to ensure that the medication is both safe and effective.[112] In the case of generic or biosimilar drugs, the producer relies on some of the data supplied by the original application for marketing authorisation with the original pharmaceutical product, to avoid doing comprehensive clinical trials.[113] The provisions to patent rights are considered such as private use or experimental purposes and use, before a patent is granted.[114]

2.3.2 Challenges to Implementation of Bolar Provisions under Health Crisis

---

<https://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm#Bolar> accessed 19 May 2021

[112] EC, Volume 2 A procedures for marketing authorisation Chapter 1 Marketing authorisation July 2019 <https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-2/vol2a_chap1_en.pdf> accessed 19 May 2021

[113] ibid.

[114] WIPO, 'Certain aspects of National/Regional Patent Laws:Exceptions and Limitations of the Rights Status as of April 2020' , <https://www.wipo.int/export/sites/www/scp/en/national_laws/exceptions.pdf> accessed 18 May 2021

Difficulties in practical use

Using TRIPS flexibilities, such as Bolar clauses, can be challenging in practice.[115] TRIPS flexibilities are used to protect public health, however the "case by case" or "product by product" approach required at the national level when employing flexibilities to overcome IP obstacles conflicts with national legislation.[116] There are expectations from trading partners, as well as a lack of practical and institutional capacity to employ TRIPS flexibilities swiftly and efficiently when health crises develop, in addition to restrictions in the national legal system.[117] As a result, suitable TRIPS-compliant safeguards must be implemented into national laws.[118] Furthermore, the measures must be practical and easy to apply.[119]

---

[115] WTO TRIPS provisions on remuneration for non-voluntary use of a patent, Section 2 , page 13, <https://www.who.int/hiv/amds/WHOTCM2005.1_OMember State.pdf> accessed 28 July 2021

[116] IP/C/672 Waiver from certain provisions of the TRIPS Agreement for the prevention, containment and treatment of COVID-19-responses to questions, paragraph 51, <https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S009-DP.aspx?language=E&CatalogueIdList=270209,270165,270173,270168,269875,269476,269346,269188,268935,268754&CurrentCatalogueIdIndex=1&FullTextHash=&HasEnglishRecord=True&HasFrenchRecord=False&HasSpanishRecord> accessed 28 July 2021

[117] ibid.

The TRIPS flexibilities in the IP system, as outlined by WIPO IPO, demonstrate the practical steps that Member States committed to at the sixth session of the Committee on Development and Intellectual Property (CDIP) to assist in understanding the flexibilities.[120] There seemed to be a sufficient number of reliable sources of guidelines to aid with various applications, such as The Medicines Law & Policy, which gives a flowchart to guide the user through the process of filing the best alternative application.[121] It provides the TRIPS Flexibilities Database with instances on implementation of the flexibilities in the national IP laws in jurisdictions such as Finland, the US and China.[122] However, with a list of extensive regulations and provisions, the best practices are left to the national authorities to comprehend and adjust.

---

[118] ibid.

[119] ibid.

[120] WIPO IPO. Flexibilities in the Intellectual Property System. <https://www.wipo.int/ip-development/en/agenda/flexibilities/> accessed 27 July 2021

[121] Medicines Law & policy, Tools, https://medicineslawandpolicy.org/wp-content/uploads/2017/05/Flowchart-Tools-MLP.pdf> accessed 30 July 2021

[122] Medicines Law &Policy, The Trips Flexibilities Database, <http://tripsflexibilities.medicineslawandpolicy.org/> accessed 30 July 2020

IP as barriers

IP tools, which many innovators used to govern the life cycle of medicinal products are, in fact, acting as barriers and affecting the timely entry to the market of generic and biosimilar medicines.[123] Secondary patents are used widely to create so-called "evergreening" strategies and Patent thickets, where multiple "follow-up" overlapping patents stating different aspects of the same product that can be filed in different jurisdictions.[124]

Further, the White Paper by Pinsent Masons, Medicines for Europe and Accord mentioned that patent thickets may contain "protection of polymorph or hydrated forms of the active substance (API) , its salts or isomeric forms, a substantially pure form of the API or an impurity formed in the manufacturing process, formulations, different concentrations of dosage forms, the manufacturing and analytical methods, the use in specific patients groups or for diagnosis, or a second medical use.” [125] In short, patent thickets around a device means that biosimilar companies are unable to switch between devices.

---

[123] EIPG, 'Barriers to generic and biosimilar entry on the market', <https://www.pharmaworldmagazine.com/barriers-to-generic-and-biosimilar-entry-on-the-market/> accessed 20 July 2021

[124] ibid.

Medecins sans frontieres(MSF) has produced a report on the impact of patents on the introduction of inexpensive vaccines in developing countries.[126] While the report focuses on pneumococcal conjugate vaccines (PCV) and the human papillomavirus (HPV) vaccine, it reveals the broad patent claims that have been applied for or granted across the entire spectrum of vaccine development, production, and use, including vaccine-production materials such as chemical reagents, host cells, vectors, and DNA/RNA sequences; vaccine compositions; process technologies; and vaccine delivery systems.[127]

---

[125] Robert Vida, Catherine Drew, Belinda Lavin, Becky Ellis, Ewan Bruce. White paper: Anatomy of a failure to launch: a review of barriers to generic and biosimilar market entry and use of competition law as a remedy, (Medicines of Europe, 4 November 2020), <https://www.medicinesforeurope.com/docs/2020.11.04-Medicines-for-Europe-Whitepaper.pdf > accessed 30 July 2021

[126] MSF, ‘MSF analysis of EU communications to TRIPS Council on COVID-19 IP waiver proposal, Technical Report (29 June 2021) <https://msfaccess.org/msf-analysis-eu-communications-trips-council-covid-19-ip-waiver-proposal> accessed 16 August 2021

[127] ibid. 47

Patents generated uncertainty, increased costs, and delayed competition, resulting in high pricing and access obstacles in developing countries. In 2016-2017, MSF filed a patent objection and later a writ petition to challenge Pfizer's vaccine composition patent, which blocked the development of alternative versions of Pfizer's PCV13 vaccine. When an identical patent was granted, a South Korean vaccine researcher was ordered to stop making PCV13. MSF's patent invalidation action against Pfizer for PCV13 remains pending in India.[128]

Unless meaningful actions are done to resolve intellectual property restrictions, a similar situation will arise with COVID-19 vaccines. Many patent filings and grants have already been discovered, including more than 100 patents on mRNA platform technologies that are employed in COVID-19 vaccines. [129]

TRIPS Plus provisions

TRIPS Plus is an official term for protecting IPRs that are not included in the requirements of TRIPS Agreements.[130]

---

[128] ibid. 48

[129] ibid. 49

[130] WHO, Impact Assessment of TRIPS Plus Provisions on Health Expenditure and Access to Medicines, (WHO, 22-24 November

These North-South trade arrangements embrace IPR chapters that oblige signing parties with higher IPR standards, which are the TRIPS-plus provisions. [131] In fact, FTAs are technologically asymmetric meaning that they are on the sole profit of countries that are net-exporters of IP related goods, whereas, net-importer countries are put to extreme burden with heavily protected goods by IPR. [132]

Further, FTAs suggest higher IP protection than TRIPS-plus provisions established, thus depriving the parties to use TRIPS flexibilities to protect public health. [133] Provisions included in FTAs compose potential challenges for the Bolar provisions. [134] Commission on Intellectual property rights,

---

2006) https://apps.who.int/iris/bitstream/handle/10665/205326/B2072.pdf> accessed 25 July 2021

[131] Wael Armouti. Evolution of data exclusivity for pharmaceuticals in Free Trade Agreements, (south centre policy brief 76, April 2020), < https://www.southcentre.int/policy-brief-76-april-2020/> accessed 30 July 2021

[132] ibid.

[133] ibid.

[134] Sisule F. Musungu (South Centre) and Cecilia Oh(World Health Organization) The use of Flexibilities in TRIPS by developing countries: can they promote access to medicines? page 3, (Commission on Intellectual property rights, innovation and public health (CIPIH) study 4C , August 2005), <

innovation and public health (CIPIH) study back in 2005 already found that FTAs between developed countries (essentially the US) and developing countries, have risk on effective use of TRIPS flexibilities in developing countries for public health purposes. [135]

One of the requirements of TRIPS plus is data exclusivity, which established a ground for governments to provide an exclusivity period for the test data developed by the originator company.[136] TRIPS-plus provides data exclusivity as it prevents registration of generic medicines for 5 years, which is not required by TRIPS.[137] Further, the cheaper generic products entering into developing countries will be delayed because of data exclusivity protection.[138] However, countries

---

https://www.who.int/intellectualproperty/studies/TRIPSFLEXI.pdf> accessed 30 July 2021

[135] ibid.

[136] Wael Armouti. Evolution of data exclusivity for pharmaceuticals in Free Trade Agreements, (south centre policy brief 76, April 2020), < https://www.southcentre.int/policy-brief-76-april-2020/> accessed 30 July 2021.

[137] WTO. Public Health protection in patent laws: selected provisions pdf., page 7, box 5.

[138] Wael Armouti. Evolution of data exclusivity for pharmaceuticals in Free Trade Agreements, (south centre policy brief 76, April 2020), < https://www.southcentre.int/policy-brief-76-april-2020/> accessed 30 July 2021.

who signed FTAs are able to mitigate its effects on public health by adjusting its national legislation such as to limit the scope and to provide exceptions to data exclusivity. [139]

Data exclusivity

Another type of IP provision that should be addressed is data exclusivity, which can have a significant negative impact on generic competition by delaying the entry of generic drugs into national and international markets.[140] Data exclusivity prohibits generic competitors from using clinical test data submitted by original pharmaceutical companies, affecting generic companies, which are typically located in developing countries and are unlikely to have the necessary funds and capabilities to replicate the time-consuming clinical trials required, for example, by the Food and Drug Administration (FDA) to prove the safety and efficacy of a certain drug. [141]

---

[139] Sisule F. Musungu (South Centre) and Cecilia Oh(World Health Organization) The use of Flexibilities in TRIPS by developing countries: can they promote access to medicines? page 3, (Commission on Intellectual property rights, innovation and public health (CIPIH) study 4C , August 2005), < https://www.who.int/intellectualproperty/studies/TRIPSFLEXI.pdf> accessed 30 July 2021

[140]

Competition policy

Competition is the antonym of monopoly, businesses should be a competitive game in a free market, with the consumers as beneficiaries.[142] During COVID-19, there are countries desperate for respirators and chemicals that are needed to test the disease, further they need their production facilities in China to produce the goods, which are being confined.[143]

All this is due to globalisation, which enhances economic growth, however it makes countries dependent on the countries with which trade happens.[144] Thus, globalisation is in its nature interdependent with each country,[145] however there are aspects that should be mitigated especially for the health crisis.

---

[141] Alessandro Pigoni, 'TRIPS-Plus Provisions and the Access to HIV Treatments in Developing Countries' (E-IR, 19 April 2020) < https://www.e-ir.info/2020/04/19/trips-plus-provisions-and-the-access-to-hiv-treatments-in-developing-countries/ > accessed 14 August 2021

[142] EC, 'What is competition policy?' <https://ec.europa.eu/competition-policy/consumers/what-competition-policy_en> accessed 17 August 2021

[143] OECD Competition Division, 'COVID-19: Fred Jenny on economic resilience and the role of competition policy in times of crisis' (22 April 2020) <https://www.youtube.com/watch?v=UR7x_ZxteUg&t=55s> accessed 14 August 2021

Fred Jenny from UN further discusses that under a health crisis, there is absolutely no time to run a full program of scientific experiments on medical clinical trials to test the most appropriate medicines against the virus, therefore the government is better to act on the intuition to reach decisions faster.[146] Both the public and private policy should act in accordance with the common goal, that the industrial policy should repatriate their allocations domestically to prevent health crises.

Positive competition policies should be adopted for a long-run, such as inter-state cooperation, across continents collaborations. To eliminate price gouging is to distribute the resources to those who really need them. Sometimes, government interventions should apply to the industry prices.

---

[144] ibid.

[145] Martin Wolf, 'Globalisation and interdependence ' (31 August 2004) <https://www.un.org/esa/documents/un.oct.2004.globalisation.and.interdepence.pdf> accessed 16 August 2021

[146] ibid.

For example, in Finland and the US, state aid is also provided during the health crisis so that industry is able to quickly restart to the domestic economic re-boost.[147] [148] On the other hand, China provided the highest ever amount of humanitarian assistance, already in over 150 countries, during COVID-19.[149]

Another aspect is that the resources should be distributed equally, meaning that people should be separated from the infected people. At the beginning of the COVID-19 pandemic, due to the fact that many countries were not prepared for such a crisis, many people were left unprotected with personal protective equipment. For example, this is impossible when Finland did not have the resources to provide FFP-class protective equipment in Finland, not because it is unnecessary but because there is a shortage of such equipment.[150] In addition, for the Finnish elderly care, many caregivers had no face-masks for all visits.[151] Such a situation occurred also in many other countries at the time, only relieved in the following months.

---

[147] Ministry of Economic Affairs and Employment, 'Temporary amendments to business development aid to continue until the end of 2021', (23 June 2021) <https://valtioneuvosto.fi/en/-/1410877/temporary-amendments-to-business-development-aid-to-continue-until-the-end-of-2021> accessed 16 August 2021

[148] Tax foundation, 'The COVID-19 Relief Bill Contains over 100 Billion USD in state Aid After All, (23 December 2020) <https://taxfoundation.org/coronavirus-relief-state-aid/> accessed 16 August 2021

[149] CSIS, ' China's Humanitarian Aid: Cooperation amidst Competition' (17 November 2020)<https://www.csis.org/analysis/chinas-humanitarian-aid-cooperation-amidst-competition> accessed 16 August 2021

---

[150] HS, 'Finnish Institute of Occupational Health: There is no reason for the widespread use of FFP-class protective equipment in Finland - They are not enough for everyone, says the expert: " A surgical mask is enough for everyday use"' (3 Feberuary 2020) <https://www.hs.fi/hyvinvointi/art-2000007779039.html> accessed 16 August 2021

[151] Yle, 'Many relatives have been frightened by faceless caregivers at the elderly - there are not enough masks for all visits, even if the instructions require it.' (15 April 2020<https://yle.fi/uutiset/3-11306112> accessed 16 August 2021

3. Developments and scenarios of Bolar exemption implementation in Finland, the US and China

The summary provides an overview of the Bolar exemption in three different countries: Finland, the United States, and China. In Finland, the Bolar exemption allows for activities necessary for obtaining marketing authorization for both generic and innovative medicines. Finland also has a data exclusivity period that provides protection to marketing authorization holders. However, access to COVID-19 vaccines in Finland is reliant on imports, and the use of the Bolar exemption for vaccine authorization remains unclear.

In the United States, the Bolar exemption was established through the Hatch-Waxman amendments. It allows activities related to the development and submission of information for FDA approval without being considered patent infringement. The exemption applies to both generic and branded pharmaceuticals and has been expanded to include medical devices.

China's Bolar exemption was initially included in its Patent Law of 1984, but its legal basis was debated until it was formally incorporated into the law in 2008. The exemption covers acts related to the production and importation of patented medicines and medical devices for the purpose of obtaining administrative approval.

In terms of COVID-19 vaccine access, the United States has authorized its own vaccines and has collaborated with various entities to expedite vaccine development. China has developed its own vaccines and has been using them domestically while distributing them to other countries.

Overall, the Bolar exemption varies in its implementation and scope across these countries. While efforts are being made at the EU level to strengthen and harmonize the exemption, the use of the exemption for COVID-19 vaccines remains uncertain. The United States and China have their own strategies for vaccine development and distribution, with China emerging as a significant vaccine producer and distributor.

3.1 The Republic of Finland

The Republic of Finland, as a member of the European Union (EU), operates under EU legislation and law enforcement. The implementation of the Bolar exemption, which allows for certain activities related to the marketing authorization of pharmaceutical products, varies among EU member states. Some countries restrict activities related to generic and biosimilar medicines, while others exempt acts for both generic and innovative medicines.

Finland falls into the category of countries that exempt acts required for marketing authorization for both generic and innovative medicines. The Finnish national legislation implemented the EU directive on Bolar exemption, amending the Finnish Patent Act and the Finnish Medicines Act. The Bolar exemption in Finland allows for examinations, experiments, and measures necessary for obtaining marketing authorization for a medicinal product related to the invention concerning that product.

In the context of pharmaceutical research and experimental use exemption, Finland has implemented a data exclusivity period. The data exclusivity period in Finland guarantees at least 8 years of exclusivity for marketing authorization holders, which can be extended to 11 years if the holder obtains authorization for new therapeutic indications that bring significant clinical benefits.

Regarding access to COVID-19 vaccines in Finland, the country imports vaccines from other countries due to the absence of domestic production. The use of the Bolar exemption to ease marketing authorization issues in Finland is unclear. Restrictions related to unfair practices and patent settlement agreements between originators and generic industries may affect access to vaccines.

The European Commission and the European Parliament are working on initiatives to strengthen and harmonize the Bolar exemption among EU member states. The aim is to increase access to generic and biosimilar medicines by revising pharmaceutical legislation and addressing market competitiveness concerns.

Overall, the Bolar exemption in Finland has improved the protection of original marketing authorization holders, and efforts are being made at the EU level to enhance access to generic and biosimilar medicines through strengthened Bolar provisions.

3.1.1 Historical development

As a member of the European Union, Finland's situation must be considered in light of EU legislation and law enforcement. In addition to the legal framework at the EU level, the practice in some other EU member states may be reflected in the European Union, the attempt to harmonise the European position is to speed up the entry of generic products, after their patent expiry, to the market.[152] On the other hand, clinical trials for generic and biosimilars are exempt from infringement, the exemption may extend to innovative products.[153] Bolar Exemption is governed by the 2001/83/EC European Directive on the Community Code to medicinal products for human use, as amended by European Directive 2004/27/EC Article 10 thereof.[154] [155]

---

[152] Dehns Patent and Trade mark attorneys, The European Bolar exemption from infringement (April 2018)

Article 10 (6) outlines patent rights infringement or supplementary protection certificates (SPCs) and that conducting necessary studies and trials with a view to applications outlined in paragraphs 1, 2, 3 and 4.[156] The implementation of the Directive is aimed to be harmonized in the EU Member State, though not entirely unformed, there are significant variances in each member state.[157]

<https://www.dehns.com/cms/document/European_Bolar_Exemption_from_Infringement.pdf> accessed 20 May 2021

[153] ibid.

[154] European Directive 2001/83/EC and 2004/27/EC Article 10.

[155] WIPO, 'Facilitating generic drug manufacturing: Bolar exemptions worldwide'(WIPO Magazine June 2021) <https://www.wipo.int/wipo_magazine/en/2014/03/article_0004.html> accessed 17 August 2021

[156] EU Directive Article 10 (6) Paragraphs 1-4, i.e. Articles 10 (1)-(4) of the Directive, concern the provision of data during the marketing approval process.

[157] ibid.

Generally speaking, there are two categories of European countries dealing with Bolar exemption. One of them is to limit activities related to marketing approval of new generic medicines, hybrid, bioequivalent and biosimilars, such as Belgium, Cyprus, Ireland, Netherlands, and Sweden.[158] The other category which exempts any act required for marketing approval and acts improving innovative medicines such as Austria, Bulgaria, the Czech Republic, Denmark, Estonia, France, Germany, Hungary, Italy, Latvia, Lithuania, Luxembourg, Malta, Poland, Portugal, Romania, Slovakia, Slovenia, and Spain.[159] Non-EU countries such as Norway and Switzerland belong to the same category. [160] Moreover, countries in Europe exempt acts regarding marketing authorisation outside the EU or European Economic Area (EAA).[161] European countries such as Finland, Germany, and Poland are included in the same category, therefore some examples are given in either court if not found in another.

---

[158] WIPO, 'Facilitating generic drug manufacturing: Bolar exemptions worldwide'(WIPO Magazine June 2021) <https://www.wipo.int/wipo_magazine/en/2014/03/article_0004.html> accessed 17 August 2021

[159] ibid.

[160] ibid.

[161] ibid.

Taken for an example in a German proceeding, The Dusseldorf Appeal of Court in the Case C-661/13 of Astellas Pharma Inc v Polypharma S.S. Pharmaceutical Works, where the CJEU was specifically asked whether the supply of patent-protected products to a generics company that intends to use the product in tests required to obtain marketing authorisation is exempt from patent infringement under Europe's Bolar provisions.[162] In particular, this question would concern the API suppliers and the European generic industry. However the answers to the question are left unknown, since the case is subsequently revolved in such a way that the referred question becomes irrelevant in this case. [163]

However, a clarification came out with a similar case CSK 92/13, Astellas v Polypharma, namely the Polish Supreme Court rejected a cassation appeal filed by Pharmaceutical Works S.A. ("Polpharma"), as a leading Polish producer of APIs and was sued by the plaintiff, Astellas Pharma Inc. for the former having infringed its patent for quinuclidin's novel derivatives, covering i.a. solifenacin succinate.[164] The issue concerned the European Bolar exemption, specifically the admissibility of a subcontractor's manufacturing of an API.[165] The Courts stressed that Polpharma, as the seller, had no control over whether the purchaser used the purchased API solely for the purposes covered by the Bolar exemption.[166] The Appeal Court states that the acts covered by the Bolar exemption may only be performed by the party applying for a marketing authorisation.[167]

---

[162] ibid.

[163] CJEU Case C-661/13

[164] CSK 92/13, Astellas v Polypharma

Even though the Unified Patent Court (UPC) frames the harmonisation in Article 27 of the UPC agreement including Bolar provisions and restrictions to exempt generic medicines, bioequivalence, and biosimilars, there are legal uncertainties about the scope and interpretation of Bolar exemptions within the EU. [168] For example, European Commission (EC) summarised effectiveness of the EU Supplementary Protection Certificates (SPC) are proven to lead generic firms to invest in its products' development outside the EU, and one of the facts is the existing (or not) of a Bolar exemption and the proximity to manufacturing. [169]

---

[165] ibid.

[166] ibid.

[167] ibid.

[168] WIPO. Facilitating generic drug manufacturing: Bolar exemptions worldwide (WIPO Magazine June 2021) <https://www.wipo.int/wipo_magazine/en/2014/03/article_0004.html>

Further, Regulation (EC) No 469/2009 is considered a force to drive manufacturers to relocate, to outsource (via licensing), their production outside the EU, where SPC protection is weaker or non-existence.[170] Even though supplying pharmaceuticals during a pandemic is secondary, companies consider supply sources of APIs affected by the scope of Bolar exemption, SPC protection, indirect patent infringement rules in the country manufacturing APIs, and compliance with regulatory standards.[171] The industry complains of the difficulty to source the API within the EU, for the occasion of generic and biosimilar-related investments.[172] [173] In addition, in non-EU countries such as Norway and Switzerland, England, and non-UPC countries such as Poland and Spain, those API restrictions may not be applicable.[174] These uncertainties lead to the conclusion that Bolar exemption may not accelerate the development of pharmaceuticals nor added value for the end-users/governments.[175]

---

[169] EC. Commission Staff Working Document, Summary of the replies to the public consultation on Supplementary Protection Certificates and patent research exemption for sectors whose products are subject to regulated market authorisations Accompanying the document Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products, Brussels, (28.5.2018) SWD (2018) 242 final, < https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=SWD:2018:0242:FIN:EN:PDF > accessed 12 April 2021

[170] ibid.

[171] ibid.

3.1.2 Implementation of the Bolar provision in Finland

Finnish national legislation implemented the directive 2004/27/EC, realised in amendments to both the Finnish Patent Act (550/1967), and the Finnish Medicines Act (295/1987) including the new data exclusivity periods. The amended Finnish Patent Act came into force on 1 May 2006 and the Finnish Medicines Act on 7 November 2005. [176]

---

[172] ibid.

[173] EC, 'Assessing the economic impact of changing exemption provisions during patent and SPC protection in Europe', <http://publications.europa.eu/resource/cellar/6e4ce9f8-aa41-11e7-837e-01aa75ed71a1.0001.01/DOC_1> accessed 12 April 2021

[174] ibid

[175] EC, 'Assessing the economic impact of changing exemption provisions during patent and SPC protection in Europe,' <http://publications.europa.eu/resource/cellar/6e4ce9f8-aa41-11e7-837e-01aa75ed71a1.0001.01/DOC_1> accessed 12 April 2021

The Bolar exemption in section 3 (3) (4) is an exemption from the exclusive rights of patent holders. The Finnish patent act section 3 list of exemptions, which constitutes patent infringement were indeed more restrictive than the activities included in Directive 2004/27/EC Article 10(6). And the following amendment were made to Finnish patent Act section 3 (3) (4):

" 3(3) the patent holder's exclusive rights do not apply to :

….

4) examinations or experiments or measures arising from practical demands which are needed for an application to obtain marketing authorisation for a medicinal product and which relate to the invention concerning that medicinal product. "[177]

---

[176] Member State. The alliance of major European law firms. Bolar provision and regulatory data exclusivity in Europe. Page 14. (2004)<https://cms.law/en/content/download/77965/2989749/version/1/file/BolarProvisioninEU.pdf> accessed 10 June 2021

[177] ibid.

3.1.3 Research and experimental use exemption in Pharmaceutical context

The data exclusivity period is implemented with Directive 2004/27/EC by amending the Finnish Medicines Act (395/1987). The new provisions of section 21a of the Medicines Act was enabled on 7 November 2005.[178]

Before the reform, Finland had the data exclusivity as 6 years and 10 years applied to high-technology products.[179] However, the reform guarantees that marketing authorisation holders obtain at least 8 years of data exclusivity in Finland, though in EU only, [180] and in total 10 years (the 8+2= 10 years rule) when related to the full dossier of information to the National Agency for Medicines (NAM). [181] The 10 year rule is extended to 11 years during the 8 years, if the marketing authorisation holder obtains an authorisation for one or more new therapeutic indications and brings significant clinical benefit compared to the existing therapies (8 +2 +1 = 11 years rule). [182] Therefore, the Bolar exception has improved the protection of the original marketing authorisation holder in Finland.

---

[178] Member State,' The alliance of major European law firms. Bolar provision and regulatory data exclusivity in Europe.' Page 14. (2004)<https://cms.law/en/content/download/77965/2989749/version/1/file/BolarProvisioninEU.pdf> accessed 10 June 2021

[179] ibid.

[180] Dr. Edward Rainsford. Maucher Jenkins. 17 October 2017. Update on Bolar exemptions in Europe. <https://www.maucherjenkins.com/news/update-on-Bolar-exemptions-in-europe> accessed 10 June 2021

[181] Member State, 'The alliance of major European law firms. Bolar provision and regulatory data exclusivity in Europe.' Page 14.

3.1.4 Access to vaccines during COVID-19

In Finland, people are getting the mRNA vaccines such as Pfizer-BioNTech Comirnaty and Moderna Spikevax. [183] The first batch of the vaccines upon arrival at the end of December, started vaccinations on 27 December with other EU countries.[184] As Finland does not manufacture COVID-19

(2004)<https://cms.law/en/content/download/77965/2989749/version/1/file/BolarProvisioninEU.pdf> accessed 10 June 2021

[182] ibid.

[183] ibid.

[184] Ministry of Social affairs and Health, 'Coronavirus and vaccine candidates' (<https://stm.fi/en/coronavirus-vaccines> accessed 17 August 2021

vaccines, it has to import the doses from other countries, the delivery is affected with marketing authorisation issues. [185] There is no research found whether the Bolar exemption is used to ease marketing authorisation issues in Finland. Further the possible restrictions might be results of Articles 101 and 102 TFEU, within which the unfair practices occur, and to produce a biannual report in this regard, as well as patent settlement agreements between originator and generic industry that may be used to impede generic market entry. [186]

However, a recent study requested by the ENVI committee document by the EC on access to medicinal products, in which MEPs asked the Commission to set up a framework to promote, guarantee, and reinforce the competitiveness and use of generic and biosimilar medicines.[187] Along with the IP Action Plan, the new Pharmaceutical Strategy for Europe recommends a revision of pharmaceutical legislation to address market competitiveness concerns and thereby increase access to generic and biosimilar medicines.[188]

---

[185] Statista, J. Clarsnitzer, 'Confirmed COVID-19 vaccine doses for Finland 2021, by manufacturer, (5 August 2021) <https://www.statista.com/statistics/1200158/confirmed-covid-19-vaccine-doses-by-manufacturer-finland/> accessed 17 August 2021

[186] EC, 'Access to medical products' <https://www.europarl.europa.eu/RegData/etudes/STUD/2021/662910/IPOL_STU(2021)662910_EN.pdf> accessed 17 August 2021

[187] ibid.

Bolar exemption will be strengthened and harmonised amongst Member States. This initiative will begin in 2021, as well as the assessment of present pharmaceutical regulation. [189]

3.2 The US

This Section focuses on the United States and covers various aspects related to the country's pharmaceutical regulations and access to vaccines during the COVID-19 pandemic.

In terms of historical development, the US has a lengthy and complex process for filing new drug applications with the FDA. However, the country provides alternative methods such as research or experimental use exemptions to regulate products. One such exemption is the Bolar exemption, which allows activities related to the development and submission of information under federal drug regulations without being considered patent infringement. This exemption was established through the Drug Price Competition and Patent

---

[188] ibid.

[189] ibid.

Term Restoration Act of 1984, also known as the "Hatch-Waxman" amendments.

The Bolar exemption originated from a court case, Roche Products, Inc. v. Bolar Pharmaceuticals Co., Inc., where Bolar imported materials for research purposes related to a generic sleeping drug before its patent expiration. The court found Bolar to be a patent infringer, highlighting the conflict between federal drug laws and patent laws. In response, Congress amended the Patent Act in 1984, providing exemptions for acts done solely to obtain and submit FDA-required information. Over time, the US courts have adopted a liberal interpretation of the Bolar provisions, expanding the scope to include medical devices and allowing exemptions even for preclinical studies.

The Bolar exemption applies equally to both generic and branded pharmaceuticals, medical devices, biologics, and biosimilars. It covers activities related to accessing information necessary for FDA approval, including pre- and post-approval activities. However, there are uncertainties regarding the boundaries and reach of the exemption.

Moving on to access to vaccines during COVID-19, the US has authorized its own COVID-19 vaccines for emergency use, including Pfizer-BioNTech, Moderna, and Janssen. In response to the pandemic, the US government has collaborated with various entities, including government agencies, international counterparts, academia, nonprofit organizations, and pharmaceutical companies, to prioritize and expedite vaccine development while maintaining scientific standards and safety. Emergency Use Authorization (EUA) has been granted by the FDA to scale up vaccine production and availability.

The US has recognized the need to reduce reliance on foreign manufacturers and strengthen domestic manufacturing capabilities, particularly in the context of shortages of protective equipment for healthcare workers. Ensuring sufficient drug manufacturing options at the national level has become crucial in light of the COVID-19 pandemic.

3.2.1 Historical development

Filing on a new drug application at the U.S. Food and Drug Administration (FDA) is a very long and arduous process, thus US law provides an alternative method for research or experimental use exemption to regulate the products.[190] This particular act sets a regulatory framework encouraging the marketing of generic pharmaceutical products.[191] Congress set the Drug Price competition and Patent Term Restoration Act of 1984, which is called the "Hatch-Waxman" amendments in common law, wherein section 271(3)(1) is then referred to as "Safe Harbour" or Bolar exemption.[192][193][194]

---

[190] Sterne Kessler, National Law Review Volume VII Number 352 December 18, 2017 Bolar exemption in North America < https://www.natlawreview.com/article/Bolar-exemptions-north-america> accessed 18 April 2021

3.2.2 Statutory exemption

The Bolar exemption originated in the US enclosing activities from patent infringement, specifically as follows in Section 271(e)(1): " It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of

---

[191] WIPO Lex. United States of America Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 et seq. (2004), <https://wipolex.wipo.int/en/legislation/details/5473> accessed 20 May 2021

[192] Hans-Rainer Jaenichen and Johann Pitz (Cold Spring Harb Perspect Med. 2015 Feb; 5(2): a020941), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4315916/> accessed 20 May 2021

[193] ibid

[194] ibid

March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site-specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products."

The act overturned a prior court ruling for not providing a research exemption: the case Roche Products, Inc. v. Bolar Pharmaceuticals Co., Inc., 733 F. 2d 858 (1984), later known as Bolar provisions. [195] The result is that the Roche v. Bolar case, also known as Safe Harbour provisions, constitutes no patent infringement, therefore applied Bolar exemptions were applied to pre-market testing with generic manufacturers who submit it to a regulatory agency. [196]

---

[195] Roche Products Inc. v. Bolar Pharmaceutical Co., 733 F.2d 858 (Fed. Cir. 04/23/1984)

[196] Anthony Tridico, Partner, Jeffrey Jacobstein, Associate, and Leythem Wall, European patent attorney, Finnegan, Henderson, Farabow, Garrett & Dunner, LLP, USA, 'Facilitating generic drug manufacturing: Bolar exemptions worldwide,' (WIPO magazine 3/2014, June 2014), <https://www.wipo.int/wipo_magazine/en/2014/03/article_0004.html> accessed 20 April 2021

So what happened in the Roche v. Bolar case? In 1983, Bolar imported 5 kg of raw materials abroad to further research, which is a requirement to obtain marketing approval from the FDA for the formulation, stability, and bioequivalence of Roche's generic sleeping drug flurazepam hydrochloride before its patent expiration date 17 January 1984, and it is deemed to infringe Roche's patent rights. [197] After the second trial, the Federal Circuit found Bolar to be a patent infringer.[198] The court recognised that it will take years for a drug to be approved for marketing authorisation and that if generic-related trials are begun after the patent expiration, the patentee will effectively be granted exclusivity beyond the patent period.[199] The Federal Circuit found that this was a conflict between federal food, drug and cosmetic law and patent law, that the courts were not the appropriate body to resolve the issue, and that the issue should be left to Congress.[200]

Further, the US Congress amended the Patent act in 1984 provided that the purpose of acts done solely for obtaining and submitting the information required by the FDA do not deem to be patent infringement.[201] Thenceforth, the US Courts have adopted an increasingly liberal interpretation with the Bolar provisions. [202] The scope of patented products has been expanded to include medical devices alongside the drugs; as it is "reasonably related" while used to collect data for FDA approval, regardless of whether it has a commercial purpose.[203] Bolar exemption can be applied even when information collected in preclinical studies is not submitted to the FD, provided that information is suitable for submission in the regular FDA process, given the relatively high probability to fail in drug screening. [204]

---

[197] Roche Products Inc. v. Bolar Pharmaceutical Co., 733 F.2d 858 (Fed. Cir. 04/23/1984)

[198] ibid.

[199] ibid.

[200] Roche Products Inc. v. Bolar Pharmaceutical Co., 733 F.2d 858 (Fed. Cir. 04/23/1984)

The US Supreme Court has ruled that the Bolar provision is not limited to experiments conducted on humans, but also on animals.[205] In Amgen vs. Roche in 2007, the US Court of Appeals for the Federal Circuit (CAFC) held that the Bolar provision could apply to both the importation of patented products and the importation of drugs manufactured by patented methods.[206]

---

[201] Hongyan Zhong, 'Chinese Bolar exemptions', (Pharmaceutical economy newspaper, 2 April 2009), <https://baike.baidu.com/reference/1211744/02782iiVbzDAaRRoVpjOzqkm7-_gho87ToG2sEpH0JtehBVq0vqi4i_oWSpBvH6XaY4MtDDsgVLeVKiWvrZNUXXas1HajJ31b5w96i6hqcZZLP0oiFA > accessed 20 April 2021

[202] ibid.

[203] ibid.

[204] ibid.

Moreover, Bolar exemption is applicable on an equal basis both for generic and branded pharmaceuticals, medical devices, biologics, and biosimilars, further exempting activities related to access information in order to have approval from FDA.[207] Those activities include pre-and post-approval, however, limited to post-approval conducts for example Momenta Pharms., Inc. v. Teva Pharms. USA Inc., 809 F. 3d

---

[205] Hongyan Zhong, ‘Chinese Bolar exemptions’, (Pharmaceutical economy newspaper, 2 April 2009), <https://baike.baidu.com/reference/1211744/02782iiVbzDAaRRoVpjOzqkm7-_gho87ToG2sEpH0JtehBVq0vqi4i_oWSpBvH6XaY4MtDDsgVLeVKiWvrZNUXXas1HajJ31b5w96i6hqcZZLP0oiFA > accessed 20 April 2021

[206] CAFC. Amgen v. Roche (2007)

[207] Paul A. Calvo, Sterne, Kessler, Goldstein & Fox P.L.L.C. ‘Bolar exemptions in North America’, (The National Law Review Volume XI Number 108, 18 April 2021)< https://www.natlawreview.com/article/Bolar-exemptions-north-america> accessed 20 April 2021

610 (Fed Cir. 2015), cert. denied sub nom. Aphastar Pharms., Inc. v. Momenta Pharms., Inc., 137 S. Ct. 68 (2016). [208]

While the exemptions provide some protection for generic drug manufacturers who prepare their products for regulatory approval, there are uncertainties arising around the statute's contours and reach.[209] As evidence in case Eli Lilly and Co. v. Medtronic, 496 US 661 (1990), the Supreme court pointed out that the exemption also applies to medical devices. [210] Further, in case Merck KgaA v. Integra Lifesciences I, Ltd., 545 U.S. 193 (2005), the Supreme Court opined that the protection of exemption is broad in its nature, allowing any pre-clinical testing of patented compounds reasonably related to the submission of information, to a regulatory agency. [211]

---

[208] Paul A. Calvo, Sterne, Kessler, Goldstein & Fox P.L.L.C. 'Bolar exemptions in North America', (The National Law Review Volume XI Number 108, 18 April 2021)< https://www.natlawreview.com/article/Bolar-exemptions-north-america> accessed 20 April 2021

[209] Anthony Tridico, Partner, Jeffrey Jacobstein, Associate, and Leythem Wall, European patent attorney, Finnegan, Henderson, Farabow, Garrett & Dunner, LLP, USA, 'Facilitating generic drug manufacturing: Bolar exemptions worldwide, (WIPO magazine 3/2014, June 2014), <https://www.wipo.int/wipo_magazine/en/2014/03/article_0004.html> accessed 20 April 2021

[210] ibid.

[211] ibid.

In addition, there is a safe harbour for certain post-marketing activities, though batch testing is excluded.[212] However, the post-approval activities might be covered by the Bolar exemption if conducted under specific requirements of the FDA.[213] [214]

3.2.3 Access to vaccines during COVID-19

The US has its own COVID-19 vaccines authorised for Emergency use Listing (EUL) such as Pfizer-BioNTech, Moderna, and Janssen.[215] In public emergencies such as COVID-19, the development process is atypical meaning that the US government has coalesced government agencies, international counterparts, academia, non profit organisations and pharmaceutical companies to jointly prioritise and to coordinate to speed up the development of vaccines, not sacrificing the scientific standards, integrity and safety. [216] For example an emergency use authorisation(EUA) can be submitted to FDA, to scale the vaccine production and availability for all.[217]

---

[212] United States Court of Appeals for the Federal Circuit 659 F.3d 1057 (Fed. Cir. 2011).

[213] Momenta Pharma., Inc. v. Teva Pharma. USA Inc., Nos. 2014-1274, -1277, -1276, and -1278 (Fed. Cir. Nov. 10, 2015).

[214] Momenta II, 809 F.3d at 621. See generally Brian Coggio and Ron Vogel, 'Federal Circuit Limits Safe Harbor for Post-Approval Conduct' LAW360 (Nov. 17, 2015). < https://www.law360.com/articles/727923/fed-circ-limits-safe-harbor-for-post-approval-conduct> Accessed 9 August 2021

[215] FDA, 'COVID-19 vaccines' (12 August 2021) <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines> accessed 17 August 2021

As a developed country, the US now realised that foreign manufacturers are to be reduced and domestic manufacturing capabilities strengthened.[218] Since the COVID-19, shortage of protective equipment is endangering health workers worldwide.[219] For the medicines, it is crucial to have drug manufacturing options at the national level. [220]

---

[216] FDA, 'Emergency use authorization for vaccines explained'.<https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained> accessed 18 Auguste 2021

[217] ibid.

[218] Brookings, 'Time to make essential medicines within the United States' (14 June 2021) <https://www.brookings.edu/blog/techtank/2021/06/14/time-to-make-essential-medicines-within-the-united-states/> accessed 17 August 2021

3.3 The People's Republic of China

This Section focuses on the People's Republic of China and explores the historical development of the Bolar exemption and its current practice, as well as access to medicines during the COVID-19 pandemic.

In China, the experimental use exemption was included in the very first Patent Law enacted in 1984. Article 62 (5) of the law stated that the use of a patent solely for scientific research and experimentation would not be considered patent infringement. The purpose of this exemption was to allow scientists and researchers the freedom to explore, evaluate, and improve technologies. However, there have been court cases, such as Glaxo v. Southwest Synthetic, where regulatory clinical trials conducted by generic companies were deemed to be patent infringement.

---

[219] WHO, 'Shortage of personal protective equipment endangering health workers worldwide', (3 March 2020)<https://www.who.int/news/item/03-03-2020-shortage-of-personal-protective-equipment-endangering-health-workers-worldwide> accessed 17 August 2021

[220] Brookings, 'Time to make essential medicines within the United States' (14 June 2021) <https://www.brookings.edu/blog/techtank/2021/06/14/time-to-make-essential-medicines-within-the-united-states/> accessed 17 August 2021

In 2006, the Beijing No. 2 Intermediate People's Court issued a non-infringement decision in the case of Co. et al. v. Beijing Wansheng Pharmaceutical Co., commonly known as the "first Bolar provision case" in China. The court referred to Article 11 of the Patent Law, which focuses on the "purpose of production and operation." The court concluded that using a patented process to manufacture a drug for administrative examination and approval did not fall within the scope of implementing the patent for production and operation, resulting in non-infringement.

These decisions sparked controversy in academic circles, with arguments regarding the lack of a legal basis for the courts to apply the Bolar provision. However, amendments to the Patent Law in 2008 formally incorporated the Bolar exemption into the legal provisions of China.

In the current practice of the Bolar exemption, the China National Intellectual Property Administration (CNIPA) published a disputed patent case that highlighted the application of the Bolar exemption. The Shanghai IP office analyzed the case and concluded that the antitumor drug sorafenib failed to demonstrate its exclusionary purpose regarding the accused product. The Chinese Patent Law distinguishes between "sell" and "offer to sell," and the disclaimer of products being in the research and development phase may not defend against offering to sell.

The Bolar exemption in China, as stated in Article 69.5 of the Patent Law, exempts certain acts from constituting patent infringement. These acts include manufacturing, using, or importing patented medicines or medical devices for the purpose of providing information required for administrative approval.

Regarding access to medicines during the COVID-19 pandemic, China has developed its own vaccines, including those produced by Sinopharm and Sinovac. These vaccines have been approved for Emergency Use Listing (EUL) and have also been included in the worldwide vaccine sharing system, Covax, which aims to provide vaccines to poorer countries. China has been using its vaccines domestically and distributing them to other countries, with Sinovac vaccines being widely used in more than 80 countries.

Despite being a middle-income developing country, China has become a producer and manufacturer of COVID-19 vaccines, contributing to global vaccination efforts. For example, more than 70% of the population in Chile has been fully vaccinated with Sinovac vaccines.

3.3.1 Historical development

In the very first Patent Law of China, the experimental use exemption was already included and enacted in 1984.[221] The 1984 Patent Law of China indicated in Article 62 (5) that the use of a patent solely for the purpose of scientific research and experimentation shall not be deemed as an act of infringement.[222] Moreover, the interpretation of the exempted use is to give scientists and researchers freedom to explore the technology, to look into the impact of the technology and to improve the technology.[223] In the case, Glaxo v. Southwest Synthetic, the court's decision favours the patentee, where regulatory clinical trials by the generic company are deemed to be patent infringement. [224]

---

[221] Patent law of the people's republic of China. Ministry of Commerce People's Republic of China. (12 March 1984) <http://english.mofcom.gov.cn/aarticle/lawsdata/chineselaw/200211/20021100050884.html >accessed 22 May 2021

[222] Patent Law of the People's Republic of China 1984 Article 62(5)

[223] ibid.

[224] Glaxo v. Southwest Synthetic

In February 2006, the Beijing No. 2 Intermediate People's Court set out the ' first Bolar provision case in China', and issued a non-infringement decision in the case of Co. et al. v. Beijing Wansheng Pharmaceutical Co. referring to Article 11 of the Patent Law, which concludes the ' purpose of production and operation'. [225] The disputed issue was on whether it is a patent infringement to use the patented process of others applied to the manufacture of a drug to meet the requirements of relevant departments for the administrative examination and approval of drugs.[226] In view of the fact that the defendant Wansheng's drug manufacture was not directly for the purpose of sale and did not fall within the scope of implementing the patent for the purpose of production and operation as set out in Article 11 of the Patent law of the People's Republic of China. [227] This resulted in the defendant's non-infringement of the patent.[228]

---

[225] ibid.

[226] ibid.

[227] Sankyo Co. et al. v. Beijing Wansheng Pharmaceutical Co. <http://new.chncase.cn:9090/case/case/1051171;jsessionid=3AC0068754277C08883C2EDF7AA0B48B > accessed 20 April 2021

[228] Sankyo Co. et al. v. Beijing Wansheng Pharmaceutical Co. <http://new.chncase.cn:9090/case/case/1051171;jsessionid=3AC0068754277C08883C2EDF7AA0B48B > accessed 20 April 2021

Further, the ‘first Bolar exemption case’ and its implementation to Patent Law Article 11 was widely opinionated, since the article was a general provision prescribing the scope of patent protection, which shall be interpreted widely. [229] The contradiction is that the adoption of the legal concept of "not directly for marketing purposes" may have a significant impact on patent protection as a whole, as such a concept is likely to open the door to a slew of new patent exceptions. [230]Article 63, on the other hand, which allows for exceptions to the patent right, has its own set of restrictions. [231] Therefore, any "limited expansion" of the exception must be read with extreme caution.[232]

In the subsequent case Eli Lilly v Gan & Lee Patent, the court again reiterated that conducting clinical trials of new drugs and applying for manufacturing licences are not acts for the purpose of production and operation. [233] [234] However, these decisions have been controversial in academic circles, with arguments concerning the lack of legal basis for the courts to apply the Bolar provision.[235]

---

[229] David Mulder et al., ‘Pharmaceutical Patent Law in Times of Crisis: A Comparative Study Part I, < https://www.taylorwessing.com/-/media/taylor-wessing/files/netherlands/eipr-2020-42-issue-9---mulder-et-al---pharmaceutical-patent-law-in-times-of-crisis-part-i.pdf> accessed 10 August 2021

[230] ibid.

[231] ibid.

[232] ibid.

Amendments to the Patent law and incorporation of the Bolar provision into the Law on 27 December 2008, the Standing Committee of the National People's Congress adopted the Decision of the Standing Committee of the National People's Congress on Amending the Patent Law of the People's Republic of China, which added a paragraph to Article 69 of the amended Patent Law (i.e. Article 63 before the amendment) as the fifth paragraph, i.e. the provision on the Bolar provision.[236] [237] Thus, the Bolar exemption was formally incorporated into the legal provisions in China . [238]

---

[233] Heyu Wu, 'The Beijing Court once again held that clinical trials of new drugs do not constitute patent infringement', (Chinese patents and trademarks 04/2007 p.92 <http://www.cpt.cn/uploadfiles/20100316101514282.pdf> accessed 20 April 2021

[234] Xiaojun Liu (Judge, Intellectual Property Division, Beijing High Court), 'New Developments in Intellectual Property Trials in 2007 at the Beijing High Court (I)', (Total No. 24 Article published by the Intellectual Property Division of the Beijing High Court, [Patent], 2007), <http://www.chinaipmagazine.com/journal-show.asp?289.html> accessed 20 April 2021

[235] Yuqing Wu, Yuwei Wang, ' "Same invention" and substantially the same scope of protection' (<http://www.cnki.com.cn/Article/CJFDTotal-FMYZ201910014.htm> accessed 20 April 2021

3.3.2 Current practice of Bolar exemption

The CNIPA published a recently disputed patent no. CN200680007187.1 "Pharmaceutical composition comprising an omega-carboxy aryl-substituted diphenyl urea for the treatment of cancer" among other IP cases honouring world IP day on 26 April 2020, Shanghai IP office has brought its significance in regard to applying for Bolar exemption. [239] Further, the Shanghai IP office finds out that the antitumor drug sorafenib subsequently fails to demonstrate its exclusion of the purpose of promoting the accused product.[240] [241]

---

[236] Patent Law of the People's Republic of China Article 69(5) (amended in 2008)

(5) Those who manufacture, use or import patented pharmaceutical products or patented medical devices for the purpose of providing information required for administrative approval, and those who manufacture or import patented pharmaceutical products or patented medical devices specifically for the purpose thereof. "

[237] Patent Law of the People's Republic of China Amendment 27 December 2008

[238] ibid.

[239] Patent no. CN200680007187.1

Moreover, the finding is in accordance with the legislation where ‘sell’ and ‘ offer to sell’ are two different acts in the Chinese Patent law, therefore the disclaimer is not able to demonstrate the difference or defend against its offering to sell. [242] Offering to sell, sell, manufacture, use, or import the patented products are five acts that are prohibited in regard to exploiting patent rights in Patent law.[243] However it is not considered a violation of patent conduct if the declaration of intent to sell is established without simultaneously finding or manufacturing or selling the patent products. [244]

---

[240] ibid., Wisdom International patent & law office. ‘Bayer anti-cancer drug Nexavar patent was challenged by Yaopharma, and finally declared invalid by CNIPA’, (Wisdom International law, 3 February 2021), <http://www.wisdomlaw.com.tw/m/405-1596-100142,c1225220 .php?Lang=en> accessed 20 April 2021

[241] Wisdom International patent & law office. ‘Bayer anti-cancer drug Nexavar patent was challenged by Yaopharma, and finally declared invalid by CNIPA’, (Wisdom International law, 3 February 2021), <http://www.wisdomlaw.com.tw/m/405-1596-100142,c1225220 .php?Lang=en> accessed 20 April 2021

[242] Article 11 Provision of the Supreme People’s Court on Issues concerning Application of Law in the Trial Cases on Patent disputes.

[243] ibid.

[244] ibid.

It is common for generic drug manufacturers to sell and promote the generic versions of patented drugs online via other platforms long before the patent expires. [245] In order to avoid being accused of patent exploitation, the manufacturer can disclaim that products are still in research and development status. [246]

When applied, Bolar exemption and Article 69.5 of Patent law indicate that the following will not constitute patent infringement, if its promotional campaign falls into the category of manufacturing, use or import targets of the specified group such as manufacturers or imports for the researchers and experimenters. [247]

To include that China's Bolar executions and the implications for the Chinese government, provided that the manufacture, use or import of patented medicines or patented medical devices for the purpose of providing information required for administrative approval, as well as the manufacture of imported patented medical devices specifically for that purpose, shall not be considered as an act of infringement.[248]

---

[245] ILO, 'Bolar exemption does not apply to offering to sell patented drugs,' (ILO, 23 November 2020), <Wisdom International patent & law office. 'Bayer anti-cancer drug Nexavar patent was challenged by Yaopharma, and finally declared invalid by CNIPA, (Wisdom International law, 3 February 2021), <http://www.wisdomlaw.com.tw/m/405-1596-100142,c1225220.php?Lang=en> accessed 20 April 2021

[246] ibid.

[247] ibid.

3.3.3 Access to medicines during COVID-19

Followed by EUL approval of vaccines as Pfizer/BioNtech Comirnaty, SII/Covishield and AstraZeneca/AZD1222, Johnson& Johnson, Moderna starting from 31 December 2020. Beijing Bio-Institute of Biological Products Co Ltd, a subsidiary of China National Biotec Group, manufactures the Sinopharm vaccine (CNBG).[249] On June 1, 2021, the Sinovac-CoronaVac was offered for EUL.[250]

Further, Sinovac and Sinopharm, two Chinese vaccine manufacturers, have joined the worldwide vaccine sharing system Covax, which aims to give vaccines to poorer countries.[251] The Global Alliance for Vaccines and Immunisation (Gavi) stated that its aim is to make 110 million doses of vaccines available for all.[252] Upon signing to Covax agreements, the Chinese vaccines are used in more than 80 countries, already being used in China and dozens of countries around the world. [253]

---

[248] ILO, 'Bolar exemption does not apply to offering to sell patented drugs', (ILO, 23 November 2020)<Wisdom International patent & law office. 'Bayer anti-cancer drug Nexavar patent was challenged by Yaopharma, and finally declared invalid by CNIPA, (Wisdom International law, 3 February 2021), <http://www.wisdomlaw.com.tw/m/405-1596-100142,c1225220.php?Lang=en> accessed 20 April 2021

[249] ibid.

[250] ibid.

Despite its status as a middle-income developing country,[254] it is itself a producer and manufacturer of the COVID-19 vaccines, also distributing the vaccines to the others; more than 70% Chileans are fully vaccinated with Sinovac vaccines. [255]

---

[251] BBC, 'Covid: What do we know about China's coronavirus vaccines?' 13 July 2021 <https://www.bbc.com/news/world-asia-china-57817591> accessed 17 August 2021

[252] ibid.

[253] ibid.

[254] IBRD IDA, ' The world bank in middle income countries', <https://www.worldbank.org/en/country/mic/overview> accessed 17 August 2021

[255] BBC, 'Covid: What do we know about China's coronavirus vaccines?' 13 July 2021 <https://www.bbc.com/news/world-asia-china-57817591> accessed 17 August 2021

4. Discussions and concluding remarks

The discussions and concluding remarks focus on the comparative law perspective, advantages and disadvantages of the Bolar provision, access to vaccines during COVID-19, and future research.

From a comparative law perspective, the challenges in interpreting the Bolar provisions in Finland, the US, and China share overlaps despite the differences in their legal systems. The purpose of patent formation is the same in all three countries, which is to grant the patentee a limited market monopoly. The countries recognize the experimental use of patented inventions and provide varying degrees of exemption from patent infringement. However, there are differences in the specific provisions and interpretations. The US has an affirmative defense Bolar exemption, while China's Bolar exemption does not apply to "offering to sell." Finland is influenced by the US Bolar exemption but faces complex issues in harmonizing and interpreting it within the EU.

The advantages of the Bolar provision include promoting early launch of generic drugs, reducing drug costs, and serving public health interests. It provides affordable drugs and devices to the public and stimulates the generic pharmaceutical industry. Suggestions for manufacturing drug companies include strengthening internal patent management, selecting suitable patents for imitation innovation, utilizing patent intelligence, and improving intellectual property literacy.

Access to vaccines during the COVID-19 pandemic has been a topic of debate. The Bolar exemption, along with TRIPS flexibilities, promotes market competition, lowers drug prices, and enhances research and development. The TRIPS-plus provisions could have affected access to vaccines if China was not a manufacturer. Developed countries like Finland, without the capacity to produce vaccines, relied on other manufacturers and international treaties. The competition policy and lack of domestic capacity in developing countries contribute to the challenges faced during health crises.

Future research on Bolar provisions is necessary to examine uncertainties and potential impacts on the innovative research field. Comparative legal studies can help balance and harmonize the application of Bolar exemption. Continuous research should be carried out to address the evolving COVID-19 pandemic and the need for countermeasures in the legal systems.

Overall, the discussions highlight the importance of Bolar provisions in facilitating access to medicines during health crises, the need for harmonization and balance, and the significance of ongoing research in this area.

4.1 Comparative law perspective

Due to the fact that the TRIPS provides a framework within which countries could act based on common approaches, despite the differential aspects and structures of the Finland, US and China landscapes, the challenges confronting the interpretation of the Bolar provisions in each national legal system have compelling overlaps. On the other hand, international agreements are usually ambiguous, leaving enough space for member economies to introduce the agreements, and to fulfil their obligations.[256] The following summarises similarities and differences addressed in respective territories.

All three governments such as Finland, China, and the US have the same purpose behind the patent formation - which is to award the patentee a limited market monopoly for divulging its invention to the public for a certain period of time. Thus, experimental use of the patented invention should not constitute patent infringement under certain circumstances such as, if the user has no intention of entering a protected market. The comparable countries, respecting the experimental use of a patented invention, are exempted from such acts of varying degrees of patent infringement.

---

[256] Cullet Philippe. Patents and Medicines: the Relationship between TRIPS and the Human Right to Health. International Affairs (Royal Institute of International Affairs 1944-) Vol. 79, No. 1 (Jan., 2003), pp. 139-160.

The original intentions of regulatory becoming Bolar exemption are similar. However, there are differences between Finland, China and the US. In the US it is the regulatory review defence, which is known as the Bolar exemption after an akin provision in US law came into force in 2005. It is understood that the Bolar exemption is an affirmative defence, therefore the defendant has the burden to establish and provide the defence during the litigation. Thus, a party seeking to rely on the Bolar exemption should keep precise and detailed records on its infringement in order to form a Bolar exemption. Besides, under Momenta, any type of quality control testing which is a habitual or regular process of production, and not relevant to obtain FDA approval, will not to be exempted.

Conversely, the Chinese IP, especially the Bolar exemption, is not applied to “offering to sell”. That is to deter opportunistic generic drug companies from monetising the patented drug before its expiration. Further, the Bolar exemption and experimental use are separate in China's codified patent law. Clearly, the Bolar exemption is not construed as specifically to experimental use exemption interpreted by Chinese Patent law. Chinese legislators did not find the use of a patent for regulatory purposes in regard to experimental use since it is not interpreted as pure philosophical use. Certainly, the act of applying for regulatory approval is deemed to be a purpose for doing business but nothing to do with philosophy.

From the European country Finland perspective, the Bolar exemption is inspired by the US equivalent. Finland is bound to employ EU directives 2001/83/EC to amend 2004/27/EC to its national laws in order to name the uncertainties pertaining to the research application exemptions in regard to the preparatory steps to obtain marketing approval. However, as many Member States in the EU, each national legislation will have its own implementation processes before the CJEU. Thus, harmonising and balancing the interpretation of the Bolar exemption in European countries such as Finland is a complex and challenging issue compared to the US and China counterparts.

Furthermore, the US and China had each of their own doctrines implied differently. Under 35 US §, 271(e)(1) Bolar exemption encompasses acts of "offering to sell" or "selling" a patented invention, whereas the Chinese statute did not include such exemptions. Chinese Bolar exemption offers competitive advantages to generic drug companies but failed to include harmonising remedies to innovative drug companies. This is because of differences in legal frames of the US and China, where the latter lacked, the former had the patent term extension for a patent that included an approved drug and a patent linkage that links patent enforcement phases with drug approval activities.

On the other hand, Finland and the US had similar challenges posed in the interpretation of the Bolar exemptions. In the US marketing approval, applicants have the broad Bolar exemption that is spared from all use that is crucial to get the marketing authorisation. Whereas in Finland, the Bolar exemption is only a referral where necessary information must be there, before getting marketing authorisation. From an international level to national implementation, the IP perspectives on post-marketing approval use and the subsequent use of patented substances under the Bolar exemption should be examined in a careful manner e.g. the limitations on the minimum protections outlined in TRIPS Agreement Article 28 and limited exceptions in Article 30.

4.2 Advantages and disadvantages of Bolar Provision

First of all, the rationale for the Bolar provision refers to the special nature of patent protection in the medical field. Secondly, the examination of regulation has an intensive relevance to public health. Thirdly, the highly technical nature of research innovations. The other aspect is legitimacy, resulting from balancing various interests. For example, promoting the early launch of generic drugs and reducing the cost of drugs and medical devices. Further, the Bolar exemption provides drugs and devices with relatively inexpensive prices, thus, the public interest is served.

The implications shall be concluded as follows; that Bolar exemption strikes the originator drug industries, stimulates positive effect on the generic pharmaceutical industries, and deems to be beneficial for the government's public health.

As well as the suggestions for the manufacturing drug companies, who shall strengthen the internal patent management of enterprises, combine with their own core competitiveness advantages, and establish a corresponding patent strategy system. Further, people should pay attention to the patents that have expired or will expire soon, combine with the advantages of the enterprise's own industrial structure, and select the patent drugs that are suitable for their imitation innovation and easy to develop.

At the same time, it is important to make full use of the patent literature of the world, actively play the role of patent intelligence, and carefully conduct a comprehensive search of patent literature before the development and production of drugs, so as to avoid the potential danger of being suspended from registration or being complained of infringement.

In addition, paying attention to the cultivation and introduction of patent talents and improving the intellectual property literacy of enterprises themselves. Member States shall actively pay attention to the policy guidance, understand and study the real-time dynamics, and be familiar with the relevant drug registration and approval process, so that we can plan reasonably and facilitate the first visit to the first drug to be approved.

Last but not least, forming IP alliances/patent pools to share patents, which can not only integrate the resources of all parties to form a complementary advantage, but also reduce the cost of research and development, and also effectively improve the technology level of enterprises and competition.

In regard to Bolar exemption on governments, the recommendations are not limited to increase incentives for new drug and medical device research, introduce timely patent term extension for drugs, and increase the protection of medicinal drugs which the government is concerned about.

4.3 Access to vaccines during COVID-19

The idea of pharmaceuticals protection, especially essential drugs and vaccines under health crisis, has been a topic of debate. In regard to TRIPS flexibilities Bolar exemption, which promotes market competition and it is needed under pharmaceutical industry to lower down lifesaving drugs at reasonable prices. In addition, it enhances research and development.

The TRIPS-plus provisions would have affected the importation of the products, thus access to vaccines, if China was not a manufacturer of the COVID-19 vaccines. On the other hand, a developed country such as Finland, who had neither the capacity to support its citizens with basic preventive equipment nor ability to produce the coronavirus vaccines, was left on the mercy of the other vaccine manufacturers and International Treaties and European Union. The US was still hit atrociously by the crisis even though it has manufactured and developed COVID-19 vaccines. The reason might be found through the competition policy, where developing country corporations tend to outsource their manufacturing facilities in developed countries or lack focus on strengthening their domestic capacity to produce essential products including medicines and equipment.

By the same token, member States of WIPO administered treaties enjoy a significant amount of leeway in carrying out their responsibilities, and experience has been gathered through the execution of all of those treaties. Some experts argue that the root of the available flexibility may be found in the TRIPS Agreement negotiating process, when Members agreed to policy autonomy for implementation since trade negotiators preferred an agreement with a lot of built-in flexibility. However the flexibilities altogether should not be used as an excuse to to avoid TRIPS responsibilities, but on the other hand, emphasis has been given to the fact that flexibilities are not always the answer to difficulties in the sphere of intellectual property, due to differences in economic development levels, among other things.

4.4 Future research

It should be noted that Bolar provisions do not alone play an important role in speeding up both the developing and developed governments' access to medicines, when the health crisis hits the country. In the future, these exemptions will continually be considered into new proposed laws or court decisions, since they influence the scope of subject matter and eligibility of the acts regarding the patent rights.

It is to be noted that balance and harmonisation within applications of Bolar exemption are needed, since critics are arguing that Bolar exemption may intercept the innovative research field. Therefore, comparative legal studies are necessary in order to examine uncertainties that experimental use laws and court decisions could possibly derive.

COVID-19 pandemic is still developing and the struggle for drugs is also in process. Continuous studies and research could be carried out based on fresh development in legal systems as required by development in countermeasures against such health crises.

Bibliography

International treaties

The Doha Agreement WTO and Health Public

The Doha Article 5(b) and (c).

World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (as amended on 23 January 2017)

The Agreement on Trade-Related Aspects of Intellectual Property Rights, 15 April 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994)

The TRIPS Agreement

The TRIPS Agreement Article 20.1 Article 29.1

The TRIPS Agreement Article 27 section 1.

The TRIPS Agreement Article 27.2

The TRIPS Agreement Article 27.3a

The TRIPS Agreement Article 27.3b

The TRIPS Agreement Article 30.
The TRIPS Agreement Article 31bis.
The TRIPS Agreement Article 33.

European Union Directives

European Union (EU) Directive Article 10 (6) Paragraphs 1-4, i.e. Articles 10 (1)-(4) of the Directive
European Directive 2001/83/EC
European Directive 2004/27/EC Article.10
European Patent Convention (EPC) Art. 87(1) and (4)

WHO 2003b; 2004c.
WTO South-East Asia, UHC Technical brief, 'Public health protection in patent laws: selected provisions' .

WIPO United States of America Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 et seq. (2004)

WIPO. SCP/27/3 Standing Committee on the Law of Patents. page 17 and 18.

WIPO. SCP/27/3 Standing Committee on the Law of Patents. page 4, objectives and goals 4.
WIPO. SCP/27/3 Standing Committee on the Law of Patents. Twenty -Seventh Session Geneva, December 11 to 15, 2017.
WIPO. SCP/31/5 Annex I, page 7 (23)

National legislation

The Republic of Finland

Directive 2004/27/EC was implemented by amending the Finnish Patent Act (550/ 967)
Finnish Medicines Act (395/1987)

The People's Republic of China

China Patent law of the People's Republic of China
China National Intellectual Property Administration
China Patent law of the People's Republic of China, industrial property (June 1993) text 2-001, page 004 Chapter 1 (9)

Chinese Patent Law Article 69(5) (amended in 2008)

The United States of America

United States Patent and Trademark office (USPTO)
USPTO. 35 U.S.C. § 102 on First Inventor to File (FITF)

Canada

DS114: Canada -Patent Protection for Pharmaceutical Products (23.10.2000).

Case law

CAFC. Amgen v. Roche (2007)
CSK 92/13, Astellas v Polypharma
CJEU Case C-661/13.
Sankyo Co. et al. v. Beijing Wansheng Pharmaceutical Co.
Roche Products Inc. v. Bolar Pharmaceutical Co., 733 F.2d 858 (Fed. Cir. 04/23/1984)

Papers

Armounti W. Evolution of data Exclusivity for pharmaceuticals in Free Trade Agreements. Policy Brief 7, April 2020 < https://www.southcentre.int/tag/trips-plus-provisions/> accessed 21 May 2021

Chen J, Nie X, Yao P, Shi L. TRIPS -plus and access to medicines in China. Journal of Public Health policy 34, 226-238(2013) < https://link.springer.com/article/10.1057/jphp.2013.13>

Gupta, Kumar Y, Meenu M, and Mohan P. 2015. The Tamiflu fiasco and lessons learnt. Indian journal of pharmacology 47 (1): 11–16. <https://doi.org/10.4103/0253-7613.150308> accessed 17 May 2021

Cullet P. Patents and Medicines: the Relationship between TRIPS and the Human Right to Health. International Affairs (Royal Institute of International Affairs 1944-) Vol. 79, No. 1 (Jan., 2003), pp. 139-160.

Jaenichen H-R, Pitz J. (Cold Spring Harb Perspect Med. 2015 Feb; 5(2): a020941)

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4315916/> accessed 20 May 2021

Jefferson, Mark A. Jones T, Doshi P, B. Del Mar C, Hama R, J. Thompson M, A. Spencer E, J. Onakpoya I, R. K. Mahtani, Nunan D, Howick J, and J. Heneghan C. 2014. Neuraminidase Inhibitors for Preventing and Treating Influenza in Adults and Children. Cochrane Database of Systematic Reviews. <https://doi.org/10.1002/14651858.cd008965.pub4.> accessed 18 May 2021

Kessler S, National Law Review Volume VII Number 352 December 18, 2017 Bolar exemption in North America < https://www.natlawreview.com/article/bolar-exemptions-north-america> accessed 18 April 2021

Kessomboon N, Limpananont J, Kulsomboon V, Maleewong U, Eksaengsri A, Paothong P. Impact on access to medicines from trips-plus: a case study of THAI.US FTA (May 2010) The Southeast Asian Journal of tropical medicine and public health 41 (3): 667.77 PubMed. < https://www.researchgate.net/publication/44800555_Impact_on_access_to_medicines_from_trips-plusA_case_study_of_THAI-US_FTA> accessed 21 May 2021

Liu X (Judge, Intellectual Property Division, Beijing High Court), 'New Developments in Intellectual Property Trials in 2007 at the Beijing High Court (I)', (Total No. 24 Article published by the Intellectual Property Division of the Beijing High Court, [Patent], 2007), <http://www.chinaipmagazine.com/journal-show.asp?289.html> accessed 20 April 2021

Malpani R. (2007) All cost no benefit: How TRIPS-Plus intellectual property rules in the US-Jordan FTA affect access to medicines. Oxford, UK: Oxfam International. Oxfam Briefing Paper No. 102, http://donttradeourlivesaway.files.wordpress.com/2011/01/all-costs-no-benefits.pdf, accessed 19 February 2013.

Nusaraporn, K., Jiraporn, L., Vidhaya, K., Usawadee, M., Achara, E. and Prinya, P. (2010) Impact on access to medicines from TRIPS-PLUS: A case study of Thai-US FTA. Southeast Asian Journal of Tropical Medicine Public Health 41 (3): 667–677.

Pastor R. The impact of free trade agreeements on intellectual property standards in a post-TRIPS world

<https://www.bilaterals.org/?the-impact-of-free-trade&lang=en> accessed 21 May 2021

Ren G. 2020. Scramble To Preorder COVID-19 Vaccines May Leave Poorer Countries Behind. Health Policy Watch. <https://healthpolicy-watch.news/scramble-to-preorder-covid-19-vaccines-may-leave-poorer-countries-behind-threatening-global-response/. > accessed 20 May 2021

Sell, Susan K. 2003. Private Power, Public Law: The Globalization of Intellectual Property Rights. Cambridge: Cambridge University Press.

Tridico A, Partner, Jacobstein J, Associate, and Wall L, European patent attorney, Finnegan, Henderson, Farabow, Garrett & Dunner, LLP, USA, 'Facilitating generic drug manufacturing: Bolar exemptions worldwide, (WIPO magazine 3/2014, June 2014), <https://www.wipo.int/wipo_magazine/en/2014/03/article_0004.html> accessed 20 April 2021

Urias, E., Ramani, S.V. Access to medicines after TRIPS: Is compulsory licensing an effective mechanism to lower drug prices? A review of the existing evidence. J Int Bus Policy 3, 3

Vejay S L. 2020. Gilead Says Remdesivir Shortages Due To Supply Chain Issues, Civil Society Argues For Wider Licensing. Health Policy Watch. 3 September. <https://healthpolicy-watch.news/gilead-says-remdesivir-shortages-due-to-supply-chain-issues-civil-society-argues-for-wider-licensing/> accessed 18 May 2021

Vijay, SvětￔLustig. 2020. Gilead Says Remdesivir Shortages Due To Supply Chain Issues, Civil Society Argues For Wider Licensing. Health Policy Watch. 3 September. <https://healthpolicy-watch.news/gilead-says-remdesivir-shortages-due-to-supply-chain-issues-civil-society-argues-for-wider-licensing/> accessed 18 May 2021

Wested J, and Minssen T. "Research and Bolar Exemptions in the US and Europe: Recent Developments and Possible Scenarios." Available at SSRN 3236127 (2018).

Wu H, 'The Beijing Court once again held that clinical trials of new drugs do not constitute patent infringement', (Chinese patents and trademarks 04/2007 p.92 <http://www.cpt.cn/uploadfiles/20100316101514282.pdf > accessed 20 April 2021

Wu Y, and Xiong Y, Comparison Of Bolar Exception In China And The United States (hina Patents & Trademarks Publications 2008)

Wu Y, Wang Y, ‘ "Same invention" and substantially the same scope of protection’ (<http://www.cnki.com.cn/Article/CJFDTotal-FMYZ201910014.htm> accessed 20 April 2021

Zhong H, ‘Chinese Bolar exemptions’, (2 April 2009) Pharmaceutical economy newspaper<https://baike.baidu.com/reference/1211744/02782iiVbzDAaRRoVpjOzqkm7-_gho87ToG2sEpH0JtehBVq0vqi4i_oWSpBvH6XaY4MtDDsgVLeVKiWvrZNUXXas1HajJ31b5w96i6hqcZZLP0oiFA > accessed 20 April 2021

Wong H. “The case for compulsory licensing during COVID-19.” (2020) Journal of global health vol. 10,1

Vida R, Drew C, Lavin B, Ellis B, Bruce E. ‘White paper: Anatomy of a failure to launch: a review of barriers to generic and biosimilar market entry and use of competition law as a remedy,’ (Medicines of Europe, 4 November 2020), <https://www.medicinesforeurope.com/docs/2020.11.04-

Medicines-for-Europe-Whitepaper.pdf > accessed 30 July 2021

Articles

Armouti W. 'Evolution of data exclusivity for pharmaceuticals in Free Trade Agreements, (south centre policy brief 76, April 2020)' < https://www.southcentre.int/policy-brief-76-april-2020/> accessed 30 July 2021

China National Intellectual Property Administration (CNIPA) < https://www.cnipa.gov.cn>accessed 09 April 2021

China Patent law of the People's Republic of China, industrial property (June 1993) text 2-001, page 004 Chapter 1 (9) <https://www.wipo.int/edocs/lexdocs/laws/en/cn/cn006en.pdf > accessed 09 April 2021

Cochrane Review < https://www.cochrane.org/> accessed 13 August 2021

CSIS, ' China's Humanitarian Aid: Cooperation amidst Competition' (17 November

2020)<https://www.csis.org/analysis/chinas-humanitarian-aid-cooperation-amidst-competition> accessed 16 August 2021

Feng L, Jiang J, Wang Y. China: Experimental use exemption of patent infringement - a brief comparison of China and the United States. (16 February 2015) Wan hui da - Peksung IP group <https://www.mondaq.com/china/patent/374754/experimental-use-exemption-of-patent-infringement--a-brief-comparison-of-china-and-the-united-states> accessed 22 May 2021

Doha WTO Ministerial 2001: TRIPS WT/MIN(01)/DEC/2 Declaration on the TRIPS agreement and public health adopted on 14 November 2001 <:https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm> accessed 20 May 2021

Eur-lex. Request for a preliminary ruling from the Tribunal d'instance de Bordeaux (France) lodged on 9 December 2013 — Thierry Delvigne v Commune de Lesparre Médoc and Préfet de la Gironde Case C-650/13 /2014/C 129/08 (Official Journal of the European Union 28 May 2014))

<https://eur-lex.europa.eu/legal-content/en/TXT/PDF/?uri=uriserv%3AOJ.C_.2014.129.01.0007.01.ENG> accessed 20 May 2021

European Union (EU) Countries <https://europa.eu/european-union/about-eu/countries_en> accessed 21 May 2021

EC, 'Commission Staff Working Document' Brussels, 28.5.2018 SWD (2018) 242 final ,<https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=SWD:2018:0242:FIN:EN:PDF> accessed 09 April 2021

EC, 'Commission staff working document of the Regulation (EC) No 469/2009 of the European Parliament and of the Council concerning the supplementary protection certificate for medicinal products, and Regulation (EC) No 1610/96 of the European Parliament and of the Council concerning the creation of a supplementary protection certificate for plant protection products (Brussels, 25.11.2020) SWD (2020) 292 Final <https://ec.europa.eu/docsroom/documents/43847/attachments/2/translations/en/renditions/native>

EC, 'Access to medical products' <https://www.europarl.europa.eu/RegData/etudes/STU

D/2021/662910/IPOL_STU(2021)662910_EN.pdf> accessed 17 August 2021

EC, ‘Assessing the economic impact of changing exemption provisions during patent and SPC protection in Europe.’ <http://publications.europa.eu/resource/cellar/6e4ce9f8-aa41-11e7-837e-01aa75ed71a1.0001.01/DOC_1> accessed 14 April 2021

EC,’Assessing the economic impact of changing exemption provisions during patent and SPC protection in Europe.’<http://publications.europa.eu/resource/cellar/6e4ce9f8-aa41-11e7-837e-01aa75ed71a1.0001.01/DOC_1> accessed 12 April 2021

EC ‘ Commission staff working document of the Regulation’ (Brussels, 25.11.2020) No 469/2009 SWD 292 Final <https://ec.europa.eu/docsroom/documents/43847/attachments/2/translations/en/renditions/native> accessed 15 August 2021

EC, ‘ Commission Staff Working Document, Summary of the replies to the public consultation on Supplementary Protection Certificates and patent research exemption for sectors whose products are subject to regulated market authorisations Accompanying the document Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products, Brussels, (28.5.2018) SWD (2018) 242 final.' < https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=SWD:2018:0242:FIN:EN:PDF > accessed 12 April 2021

EC, 'Volume 2 A procedures for marketing authorisation Chapter 1 Marketing authorisation' (July 2019)<https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-2/vol2a_chap1_en.pdf> accessed 19 May 2021

EC, 'What is competition policy?' <https://ec.europa.eu/competition-policy/consumers/what-competition-policy_en> accessed 17 August 2021

EIPG, 'Barriers to generic and biosimilar entry on the market', <https://www.pharmaworldmagazine.com/barriers-to-

generic-and-biosimilar-entry-on-the-market/> accessed 20 July 2021

FDA, 'COVID-19 vaccines' (12 August 2021) <https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/covid-19-vaccines> accessed 17 August 2021

FDA, 'Emergency use authorization for vaccines explained'.<https://www.fda.gov/vaccines-blood-biologics/vaccines/emergency-use-authorization-vaccines-explained> accessed 18 Auguste 2021

IBRD IDA, ' The world bank in middle income countries', <https://www.worldbank.org/en/country/mic/overview > accessed 17 August 2021

ILO, 'Bolar exemption does not apply to offering to sell patented drugs, (ILO, 23 November 2020), <Wisdom International patent & law office. 'Bayer anti-cancer drug Nexavar patent was challenged by Yaopharma, and finally declared invalid by CNIPA, (Wisdom International law, 3 February 2021), <http://www.wisdomlaw.com.tw/m/405-1596-100142,c1225220 .php?Lang=en> accessed 20 April 2021

IP/C/672 Waiver from certain provisions of the TRIPS Agreement for the prevention, containment and treatment of COVID-19-responses to questions, paragraph 51, <https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S009-DP.aspx?language=E&CatalogueIdList=270209,270165,270173,270168,269875,269476,269346,269188,268935,268754&CurrentCatalogueIdIndex=1&FullTextHash=&HasEnglishRecord=True&HasFrenchRecord=False&HasSpanishRecord> accessed 28 July 2021

Medicines Law &Policy, The Trips Flexibilities Database, <http://tripsflexibilities.medicineslawandpolicy.org/> accessed 30 July 2020

Medicines Law & policy, Tools, https://medicineslawandpolicy.org/wp-content/uploads/2017/05/Flowchart-Tools-MLP.pdf> accessed 30 July 2021

Ministry of Economic Affairs and Employment, 'Temporary amendments to business development aid to continue until the end of 2021', (23 June 2021) <https://valtioneuvosto.fi/en/-/1410877/temporary-

amendments-to-business-development-aid-to-continue-until-the-end-of-2021> accessed 16 August 2021

Ministry of Social affairs and Health, 'Coronavirus and vaccine candidates' (<https://stm.fi/en/coronavirus-vaccines> accessed 17 August 2021

MSF, 'MSF analysis of EU communications to TRIPS Council on COVID-19 IP waiver proposal, Technical Report (29 June 2021) <https://msfaccess.org/msf-analysis-eu-communications-trips-council-covid-19-ip-waiver-proposal> accessed 16 August 2021

Momenta II, 809 F.3d at 621. See generally Brian Coggio and Ron Vogel, 'Federal Circuit Limits Safe Harbor for Post-Approval Conduct' LAW360 (Nov. 17, 2015). < https://www.law360.com/articles/727923/fed-circ-limits-safe- harbor-for-post-approval-conduct> Accessed 9 August 2021

Musungu S.F. (South Centre) and Oh C.(World Health Organization), 'The use of Flexibilities in TRIPS by developing countries: can they promote access to medicines? page 3,' (Commission on Intellectual property rights, innovation and public health (CIPIH) study 4C , August 2005), <

https://www.who.int/intellectualproperty/studies/TRIPSFLEXI.pdf> accessed 30 July 2021

OECD Competition Division, 'COVID-19: Fred Jenny on economic resilience and the role of competition policy in times of crisis' (22 April 2020) <https://www.youtube.com/watch?v=UR7x_ZxteUg&t=55s> accessed 14 August 2021

Opinion of the Economic and Social Committee on the "Proposal for a Directive of the European Parliament and of the Council on the patentability of computer-implemented inventions" (COM(2002) 92 final - 2002/0047 (COD)) Official Journal C 061, 14/03/2003 P. 0154 -0163 Section 1.1

Patent no. CN200680007187.1

Pigoni A. 'TRIPS-Plus Provisions and the Access to HIV Treatments in Developing Countries' (E-IR, 19 April 2020) < https://www.e-ir.info/2020/04/19/trips-plus-provisions-and-the-access-to-hiv-treatments-in-developing-countries/ > accessed 14 August 2021

Sankyo Co. et al. v. Beijing Wansheng Pharmaceutical Co.<http://new.chncase.cn:9090/case/case/1051171;jsessi

onid=3AC0068754277C08883C2EDF7AA0B48B > accessed 20 April 2021

Tax foundation, 'The COVID-19 Relief Bill Contains over 100 Billion USD in state Aid After All, (23 December 2020) <https://taxfoundation.org/coronavirus-relief-state-aid/> accessed 16 August 2021

Tridico A, Partner, Jacobstein J, Associate, and Wall L, European patent attorney, Finnegan, Henderson, Farabow, Garrett & Dunner, LLP, USA, 'Facilitating generic drug manufacturing: Bolar exemptions worldwide, (WIPO magazine 3/2014, June 2014), <https://www.wipo.int/wipo_magazine/en/2014/03/article_0004.html> accessed 20 April 2021

UNAIDS, 'Box 3: WIPO study on patent-related flexibilities in 142 countries'<https://www.unaids.org/sites/default/files/media_asset/JC2049_PolicyBrief_TRIPS_en_1.pdf> accessed 17 May 2021

Wolf M, 'Globalisation and interdependence ' (31 August 2004) <https://www.un.org/esa/documents/un.oct.2004.globalisation.and.interdepence.pdf> accessed 16 August 2021

UNDP, 'COVID-19 Pandemic Humanity needs leadership and solidarity to defeat COVID-19 <https://www1.undp.org/content/brussels/en/home/coronavirus.html> accessed 13 August 2021

USPTO. 35 U.S.C. § 102 on First Inventor to File (FITF) ,<https://www.uspto.gov/patents/first-inventor-file-fitf-resources> accessed 09 April 2021

WHO, 'Access to affordable medicines for HIV/AIDS and hepatitis: the intellectual property rights context. 3. TRIPS flexibilities and compulsory licensing.' <https://apps.who.int/iris/bitstream/handle/10665/204741/B5144.pdf?sequence=1> accessed 14 May 2021

WHO, Impact Assessment of TRIPS Plus Provisions on Health Expenditure and Access to Medicines, (WHO, 22-24 November 2006) https://apps.who.int/iris/bitstream/handle/10665/205326/B2072.pdf> accessed 25 July 2021

WHO, 'Shortage of personal protective equipment endangering health workers worldwide', (3 March 2020)<https://www.who.int/news/item/03-03-2020-shortage-of-personal-protective-equipment-endangering-health-workers-worldwide> accessed 17 August 2021

WHO, 'The Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property' <https://www.who.int/phi/implementation/phi_globstat_action/en/>accessed 14 May 2021

WHO OMC, 'TRIPS and Pharmaceutical Patents', < https://www.wto.org/english/tratop_e/trips_e/tripsfactsheet_pharma_e.pdf> accessed 14 August 2021

WHO, 'WHO announces COVID-19 outbreak a pandemic', (12 March 2020) < https://www.euro.who.int/en/health-topics/health-emergencies/coronavirus-covid-19/news/news/2020/3/who-announces-covid-19-outbreak-a-pandemic> accessed 13 August 2021

WIPO, 'Certain aspects of National/Regional Patent Laws:Exceptions and Limitations of the Rights Status as of April 2020' , <https://www.wipo.int/export/sites/www/scp/en/national_laws/exceptions.pdf> accessed 18 May 2021

WIPO Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 et seq.<https://wipolex.wipo.int/en/legislation/details/5473> accessed 20 May 2021

WIPO, ‘Facilitating generic drug manufacturing: Bolar exemptions worldwide’(WIPO Magazine June 2021) <https://www.wipo.int/wipo_magazine/en/2014/03/article_0004.html> accessed 17 August 2021

WIPO IPO. Flexibilities in the Intellectual Property System. <https://www.wipo.int/ip-development/en/agenda/flexibilities/> accessed 27 July 2021

WTO, 'DS114: Canada — Patent Protection of Pharmaceutical Products' (World Trade Organization, 23 October 2000) <https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds114_e.htm> accessed 19 May 2021

WTO TRIPS provisions on remuneration for non-voluntary use of a patent, Section 2 , page 13, <https://www.who.int/hiv/amds/WHOTCM2005.1_OMember State.pdf> accessed 28 July 2021

WTO,’ Chapter 4: Medical technologies: the access dimension <https://www.wto.org/english/tratop_e/trips_e/trilatweb_e/ch4a_trilat_web_13_e.htm > accessed 20 May 2021

WTO, ‘ TRIPS and publish health’ <https://www.wto.org/english/tratop_e/trips_e/pharmpatent_e.htm> accessed 19 May 2021

WTO, ‘TRIPS provisions on remuneration for non-voluntary use of a patent’<https://www.who.int/hiv/amds/WHOTCM2005.1_OMember State.pdf> accessed 28 July 2021.

Wu H, ‘The Beijing Court once again held that clinical trials of new drugs do not constitute patent infringement’, (Chinese patents and trademarks 04/2007 p.92 <http://www.cpt.cn/uploadfiles/20100316101514282.pdf> accessed 20 April 2021

WTO, 'Fact Sheet: TRIPS and Pharmaceutical Patents Obligations and exceptions' (World Trade Organization, 2021) <https://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm#bolar> accessed 19 May 2021

WTO Chapter 4: Medical technologies: the access dimension <https://www.wto.org/english/tratop_e/trips_e/trilatweb_e/ch4a_trilat_web_13_e.htm#_ednref19> accessed 20 May 2021

WTO, ‘Agreement on Trade-Related Aspects of Intellectual Property- Rights (as amended on 23 January 2017) <https://www.wto.org/english/docs_e/legal_e/31bis_trips_01_e.htm>accessed 19 May 2021

Other resources

Bowman E, and Valentine A. ‘ Biden Backs Waiving International Patent Protections For COVID-19 Vaccines’, (NPR, 5 May 2021), < https://www.npr.org/sections/coronavirus-live-updates/2021/05/05/993998745/biden-backs-waiving-international-patent-protections-for-covid-19-vaccines?t=1628880651447> accessed 13 August 2021

BBC, ‘Covid: What do we know about China’s coronavirus vaccines?’ 13 July 2021 <https://www.bbc.com/news/world-asia-china-57817591> accessed 17 August 2021

BBC,’ Sinopharm: Chinese covid vaccine gets WHO emergency approval‘(7 May 2021)<https://www.bbc.com/news/world-asia-china-56967973> 22 May 2021

BBC, ‘Covid: What do we know about China’s coronavirus vaccines?’ 13 July 2021 <https://www.bbc.com/news/world-asia-china-57817591> accessed 17 August 2021

Brookings, ‘Time to make essential medicines within the United States’ (14 June 2021) <https://www.brookings.edu/blog/techtank/2021/06/14/time-to-make-essential-medicines-within-the-united-states/> accessed 17 August 2021

CMS. The alliance of major European law firms. Bolar provision and regulatory data exclusivity in Europe. Page 14. (2004)<https://cms.law/en/content/download/77965/2989749/version/1/file/BolarProvisioninEU.pdf> accessed 10 June 2021

Dehns Patent and Trade mark attorneys, The European Bolar exemption from infringement (April 2018) <https://www.dehns.com/cms/document/European_Bolar_Exemption_from_Infringement.pdf> accessed 20 May 2021

HS, ‘Finnish Institute of Occupational Health: There is no reason for the widespread use of FFP-class protective equipment in Finland - They are not enough for everyone, says the expert: " A surgical mask is enough for everyday use"' (3 February 2020) <https://www.hs.fi/hyvinvointi/art-2000007779039.html> accessed 16 August 2021

Madhok D. India's Covid-19 catastrophe could make global shortages even worse (11 May 2021) CNN Business <https://edition.cnn.com/2021/05/10/business/india-covid-industries-intl-hnk/index.html> accessed 22 May 2021

Matej Mikulic, U.S. pharmaceutical industry - statistics & facts. Statista (20 November 2020) <https://www.statista.com/topics/1719/pharmaceutical-industry/> accessed 14 July 2021

Mulder D., et al., 'Pharmaceutical Patent Law in Times of Crisis: A Comparative Study Part I, < https://www.taylorwessing.com/-/media/taylor-wessing/files/netherlands/eipr-2020-42-issue-9---mulder-et-al---pharmaceutical-patent-law-in-times-of-crisis-part-i.pdf> accessed 10 August 2021

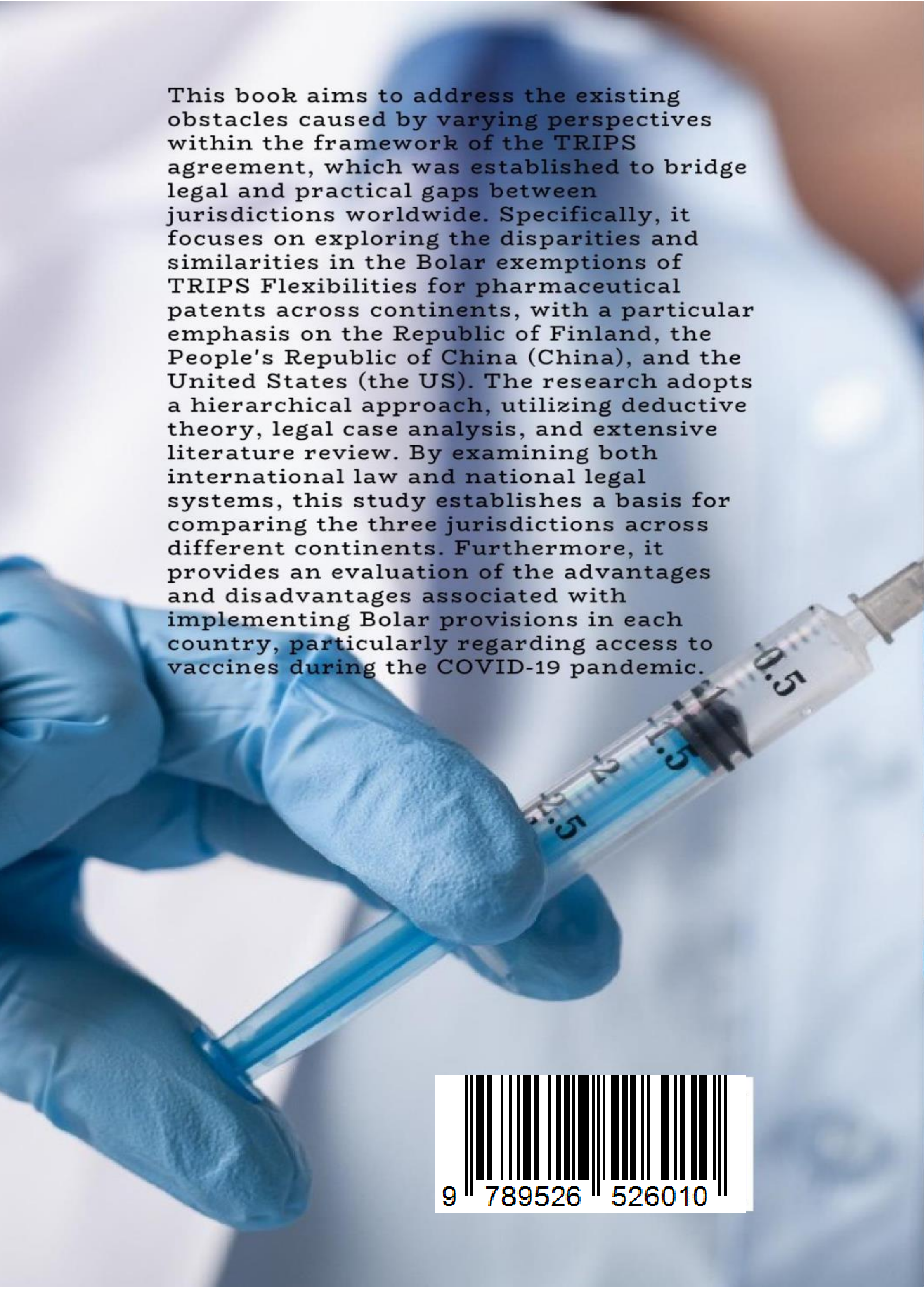
Statista, J. Clarsnitzer, 'Confirmed COVID-19 vaccine doses for Finland 2021, by manufacturer, (5 August 2021) <https://www.statista.com/statistics/1200158/confirmed-

covid-19-vaccine-doses-by-manufacturer-finland/> accessed 17 August 2021

Wisdom International patent & law office. 'Bayer anti-cancer drug Nexavar patent was challenged by Yaopharma, and finally declared invalid by CNIPA, (Wisdom International Law, 3 February 2021), <http://www.wisdomlaw.com.tw/m/405-1596-100142,c1225220 .php?Lang=en> accessed 20 April 2021

Ulick J. Why India's second covid-19 surge is much worse than its first. (15 May 2021) Wall Street Journal <https://www.wsj.com/articles/why-indias-second-covid-19-surge-is-much-worse-than-its-first-11621071001> accessed 22 May 2021

Yle, 'Many relatives have been frightened by faceless caregivers at the elderly - there are not enough masks for all visits, even if the instructions require it.' (15 April 2020<https://yle.fi/uutiset/3-11306112> accessed 16 August 2021



This book aims to address the existing obstacles caused by varying perspectives within the framework of the TRIPS agreement, which was established to bridge legal and practical gaps between jurisdictions worldwide. Specifically, it focuses on exploring the disparities and similarities in the Bolar exemptions of TRIPS Flexibilities for pharmaceutical patents across continents, with a particular emphasis on the Republic of Finland, the People's Republic of China (China), and the United States (the US). The research adopts a hierarchical approach, utilizing deductive theory, legal case analysis, and extensive literature review. By examining both international law and national legal systems, this study establishes a basis for comparing the three jurisdictions across different continents. Furthermore, it provides an evaluation of the advantages and disadvantages associated with implementing Bolar provisions in each country, particularly regarding access to vaccines during the COVID-19 pandemic.

9 789526 526010